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Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes

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ASSOCIATIONS BETWEEN PHYSICAL ACTIVITY, HEALTH-RELATED QUALITY OF LIFE, REGIMEN ADHERENCE, AND GLYCEMIC CONTROL IN JORDANIAN ADOLESCENTS WITH TYPE 1 DIABETES

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIRMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

CIZIK SCHOOL OF NURSING

BY

YOUSEF M. ALJAWARNEH, Ph.D.(c), M.C.B., R.N.

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To the Dean for the School of Nursing:

I am submitting a dissertation written by Yousef Mahmoud Aljawarneh and entitled "Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Geri L. Wood, PhD, RN, FAAN, Committee Chair

We have read this dissertation
and recommend its acceptance:

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ABSTRACT

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Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes

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Background: Adolescents with Type 1 Diabetes (T1D) display a greater than two-fold higher risk of developing diabetes-related complications compared with the their healthy peers and the risk increases markedly as glycated hemoglobin (HbA1c) increases. The majority of the findings on the associated factors with improved glycemic control are geared toward Western population with a clear lack of studies on Middle Eastern populations. **Purpose:** This study aimed to examine the effect of Physical Activity (PA), Health-Related Quality of Life (HRQoL), and regimen adherence on glycemic control in Jordanian adolescents with T1D. **Methods:** The study utilized a cross-sectional design. Jordanian adolescents (aged 12-18) with T1D (n=74) were recruited. Self-reported measures were used including the Pediatric Quality of Life-Diabetes Module, the International Physical Activity Questionnaire, and the Summary of Diabetes Self-Care Activities. HbA1c values were obtained from the medical records. Correlation analyses were conducted using Pearson's and Spearman's correlation tests. Multiple regression analyses were conducted to determine if HRQoL, PA, and regimen adherence predict glycemic control. **Results:** Only 14.8% of the participants demonstrated good glycemic control (HbA1c $\leq$ 7.5%). Participants with poor control had a statistically significant lower mean PA of MET-minutes/week (3531.9 ± 1356.75 vs. 1619.81 ± 1481.95, $p <$ .001) compared to those with good control. The total sample was found to demonstrate

low HRQoL (47.70 ± 10.32). Participants were within the acceptable range of PA (1885.38 ±1601.13) MET-minutes/week. HbA1c significantly inversely correlated with PA (r = -.328, p = .010) and regimen adherence (r = -.299, p = .018). Regimen adherence and PA significantly predicted HbA1c in the unadjusted regression model (β = -.367, p < .01; β = -.409, p < .01) and after adjustment for age and disease duration (β = -.360, p < .01; β = -.475, p < .01). In the interaction model, the interaction between PA and regimen adherence was statistically significant (β = -.304, p < .05). **Conclusion:** Better glycemic control was significantly predicted by higher PA and regimen adherence levels. There was no significant association between glycemic control and HRQoL. Further research is needed to provide more information on psychosocial and cultural factors that impact glycemic control and quality of life in this population

Keywords: adolescents, glycemic control, physical activity, quality of life, regimen adherence, type 1 diabetes.

Summary

The dissertation study entitled "Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes" is presented in this book. The purpose of the study was to examine the associations between PA, HRQoL, regimen adherence, and glycemic control in Jordanian adolescents (aged 12-18) with T1D and to determine if HRQoL, PA, and regimen adherence predict glycemic control while adjusting for age and disease duration in this population. This book includes the proposal of the study, the final manuscript describing the background, the purpose statement, the statement of the problem, the specific aims and hypotheses, the conceptual framework, methods, statistical analyses, results, discussion, conclusions, and recommendations. The book also includes a manuscript submitted for publication in the BMC Health Services Research Journal and entitled "Arabic Translation and Psychometric Evaluation of the Adherence in Diabetes Questionnaire in Jordanian Adolescents with Type 1 Diabetes: Proposal and Protocol". The appendixes contain the Institutional Review Board (IRB) approvals, consent forms, study flyers, instruments used for data collection, and the detailed study protocol. The final section of the dissertation is the curriculum vitae of the researcher.

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ABSTRACT

Background: Poor glycemic control in adolescents with Type 1 Diabetes (T1D) increases the risk for microvascular and macrovascular complications. Several predictors have been found to be significantly correlated with better glycemic control; however, the findings are geared to a Western population with a clear lack of studies on Middle Eastern populations. This study aims to assess the correlation of glycemic control and adherence, health-related quality of life (HRQoL), and physical activity (PA) in Jordanian adolescents with T1D. **Research Design and Methods:** This is a cross-sectional study. A convenience sample of 74 T1D adolescents (aged 12-18) will be recruited from King Abdullah University Hospital in Jordan. Clinical and personal data will be collected. Self-reported measures will be used; the Pediatric Quality of Life-Diabetes Module for HRQoL, the International Physical Activity Questionnaire for PA, and the Summary of Diabetes Self-Care Activities for adherence. Data on the glycemic control will be obtained from the medical records. **Data Analysis:** Data will be summarized according to each instrument's scoring criteria. Descriptive statistics will be used to calculate percentages and counts for categorical variables, and means and standard deviations for continuous variables. The Pearson correlation coefficient will be computed to examine the correlations between the variables. The generalized linear model test will be used to examine the predictability of PA, HRQoL, and adherence on glycemic control. **Future Implication:** Better understanding of how PA, HRQoL, and adherence impact glycemic control will enable researchers and clinicians to design interventions that promote these factors and positively improving clinical outcomes in this population.

Specific Aims

Traditionally, the management of Type 1 Diabetes (T1D) has relied heavily on the pharmacological treatment components to minimize and prevent medical complications. However, the medical approach has changed to emphasize the importance of including all health dimensions including social, psychological, and emotional components of patients' life. Controlling blood glucose levels and improving glycemic control in adolescents with T1D substantially decreases the risk of macro and microvascular complications (Demirel, Tepe, Kara, & Esen, 2013). Therefore, the guidelines of T1D treatment intensify controlled glycemic status (Cheng et al., 2013; American Diabetes Association [ADA], 2014), which is measured by the glycohemoglobin (HbA1c) level, a measure of the average level of blood sugar over the past 2 to 3 months (Hanas & John, 2010). Despite the fact that the recommended level of less than 7.5% is generally associated with decreased risk of diabetes complications compared with higher levels, few of the adolescents with T1D achieved this target (Livingstone et al., 2012). Patient adherence is important for effective outcomes of any medical treatment. Failure to adhere to diabetes treatment regimens can worsen glycemic control that can lead to negative clinical outcomes (Borus & Laffel, 2010). The presence of a chronic condition such as T1D during adolescence leads to significant stress and anxiety that is associated with risk for behavioral and emotional problems and hindrance with adherence to therapeutic regimens (Compas, Jaser, Dunn, & Rodriguez, 2012).

Quality of life is considered as an important component of chronic disease treatment. Also, more emphasis has been given to assessing, monitoring, and studying the health-related quality of life (HRQoL) of adolescents with T1D (Abdul-Rasoul, AlOtaibi, Abdulla, Rahme, & AlShawaf, 2013). Moreover, adolescents with T1D and their parents

congruously demonstrated lower HRQoL scores compared with healthy people of the same age and gender (Özyazıcıoğlu, Avdal, & Sağlam, 2017).

Physical activity (PA) is considered an essential component of the management of T1D for decades. Several studies found an inverse correlation between PA and HbA1c levels (Herbst et al., 2007; Herbst, Bachran, Kapellen, & Holl, 2006). In contrast, several meta-analyses reported contradictory results, while Quirk and colleagues (2014) suggested an improvement in the glycemic status of physically active adolescents with T1D, Kennedy and colleagues (2013) did not find an association between glycemic control and PA in adolescents with T1D.

The majority of research on T1D has been conducted in North America and Europe with very little research conducted in the Middle East. Given the differences in health care delivery systems, cultural components, family structure, and religion orientations in different countries, the findings of these existing studies may not be generalizable to Middle Eastern adolescents. Therefore, the present study seeks to address this gap by examining the effect of PA, HRQoL, and adherence on glycemic control in Jordanian adolescents (aged 12-18) with T1D. The present study represents the starter of a long-term research trajectory aimed on understanding the various individual, psychosocial, and physiological factors that impact the glycemic control in this population. Further research in this population will hopefully provide more information and understanding of the factors that facilitate disease management and develop interventions that can improve medical and psychosocial outcomes of T1D. Study aims and hypotheses are as follows:

Aim 1: Examine the association between PA and glycemic control in Jordanian adolescents with T1D. *Hypothesis 1.1*: Adolescents having high PA levels would have a glycemic control ≤ 7.5% as measured by HbA1c, independent of age and disease duration. Aim 2: Evaluate HRQoL of Jordanian adolescents with T1D and examine gender and its association with glycemic control. *Hypothesis 2.1*: There are significant gender differences in adolescent HRQoL (specifically, girls have poorer self-rated HRQoL than boys), independent of age and disease duration. *Hypothesis 2.2:* Adolescents having low HRQoL scores would exhibit high levels of glycemic control (HbA1c ≥ 9%), independent of age and disease duration. Aim 3: Examine the association between regimen adherence and glycemic control in Jordanian adolescents with T1D. *Hypothesis 3.1:* Adolescents with high adherence scores would have a glycemic control ≤ 7.5% as measured by HbA1c, independent of age and disease duration. Aim 4: Examine the interaction between PA, HRQoL, and adherence in the prediction of glycemic control in Jordanian adolescents with T1D. *Hypothesis 4.1:* The HRQoL will interact with adherence in the prediction of glycemic control with higher scores in both variables predict a glycemic control of ≤ 7.5% as measured by HbA1c. *Hypothesis 4.2:* The HRQoL will interact with PA in the prediction of glycemic control with higher scores in both variables predict a glycemic control of ≤ 7.5% as measured by HbA1c. *Hypothesis 4.3:* There will be no interaction between PA and adherence in the prediction of glycemic control in Jordanian adolescents with T1D.

Research Strategy

Significance

Type 1 diabetes is an autoimmune disease affecting children and adolescents and considered as the second most common chronic condition in this population. About 1.25

million Americans are living with T1D including about 200,000 youth (less than 20 years old) (Centers for Disease Control and Prevention, 2014). Prevalence and incidence of T1D vary between countries (Maahs, West, Lawrence, & Mayer-Davis, 2010). In the Arab world, there is clear epidemiological evidence that the incidence of T1D is high (Elhadd, Al-Amoudi, & Alzahrani, 2007), particularly in the Gulf region with large variations in the incidence, ranging from low in Oman (2.54/100,000) (Soliman, al-Salmi, & Asfour, 1996) to high in Saudi Arabia (29/100,000) (Habeb et al., 2011). Several factors play a major role in these variations such as culture, vast gap in socioeconomic status, wide geographical range, and high rates of first-cousin marriage and endogamy which created several inbreeding communities with increased homozygosity of both the human leukocyte antigen (HLA) haplotypes and non-HLA genes associated with susceptibility to T1D among Arabs (Zayed, 2016).

Relatively, Jordan has a low incidence of T1D, but it is increasing (Ajlouni, Khader, Batieha, & El-Khateeb, 2008).The majority of the populations of Jordan are of Arab origin. Two minority groups immigrated to Jordan 140 years ago; Circassian and Chechen with a total population of 80,000 and 30,000 respectively. A study conducted in 2012 by Dajani et al, found that the prevalence of T1D among Circassians and Chechens was higher than in the Jordanian population. The study concluded that factors such as genetic predisposition, lifestyle, and unhealthy dietary pattern were related to these differences.

Adolescence is a theoretical construct that is dynamically evolved through biological, psychological, social, cultural and transitory perspectives (Curtis, 2015). This developmental period is classically known as the time between the onset of puberty and

beginning of social independence (Steinberg, 2014). Adolescence is broadly defined using the chronological definition that includes the age of 10 to 19; however, the range may include a wider span of 9 to 26 years depending on the source (Curtis, 2015). In contrast, the World Health Organization believes that the chronological definition of adolescence is only one aspect that describes this period of development and a more functional definition based on the biopsychosocial characteristics should be considered (WHO, 2003).

While the appreciation for the developmental variability is essential when studying adolescence, confusion may arise in the construction of adolescent research due to inconsistencies in the inclusion criteria. Therefore, the operational definition of adolescence chronology of 12 to 18 years will be employed in this study. Certainly, a great developmental variance occurs between the ages of 12 through 18 years and thus adolescents can be divided into sub-stages; early adolescence as approximately 12 to 14 years, and late adolescence as approximately 15 to 18 years (Irwin, Burg & Cart, 2002). Early adolescence is broadly described by the onset of physical and sexual maturation accompanied with early cognitive development. These changes can be a source of anxiety and excitation as their body is undergoing the transformation (Radzik, Sherer, & Neinstein, 2002). At this stage, boys and girls start making adjustments to behaviors to fit with perceived norms (Steinberg, 2014). In late adolescence, the brain continues to develop with increased capacity for reflective and analytical thoughts. Also, adolescents at this stage develop the ability to evaluate risks and make reasonable decisions, seek greater autonomy, and being independence from adult guardians (Garrison & Felice, 2009). In respect to T1D, these age-related differences may contribute to disagreements

between parents and their adolescents with T1D regarding diabetes care responsibilities (Helgeson, Becker, Escobar, & Siminerio, 2012; Nordfeldt et al., 2013). The presence of diabetes in adolescence can be an additional source of stress and potentially exposes teens to negative experiences that can influence their social, emotional, and developmental aspects of their lives (De Wit et al., 2007).

Adherence is a concept widely used to reflect a patient's ability to follow healthcare advice and achieve effective clinical outcomes. World Health Organization (WHO) defined adherence as "the extent to which a person's behavior (taking medications, following a recommended diet and/or executing lifestyle changes) corresponds with the agreed recommendations of health professionals" (2003, p.3).As recognized in Healthy People 2020 goals, improving glycemic control among persons with diabetes requires an increased focus on non-adherence risk factors and puts more emphasis on behavioral and psychosocial components of diabetes self-management (Office of Disease Prevention and Health Promotion, 2016). Patients with diabetes are recommended to adhere to many self-management behaviors to prevent diabetes-associated complications (American Association of Diabetes Educators, 2014). In case of T1D, this is considered a challenge where patients must meet the demands of lifelong disease management (ADA, 2014).

Poor adherence to diabetic therapeutic regimens seems to result from a multifactor combination of factors that may derail health outcomes (Cox & Hunt, 2015). Moreover, adolescents with T1D are less adherent to blood glucose monitoring, insulin therapy, diet, and PA compared with children (Patton, 2011). The measurement of diabetes regimen adherence is typically accomplished by calculating the number of times

the patient takes insulin, checks blood glucose levels, regulates carbohydrates intake, and performs physical activities as recommended (Garcia-Pérez, Álvarez, Dilla, Gil-Guillén & Orozco-Beltrán, 2013). Therefore, adherence to such complex treatment regimens challenges even the most competent and motivated adolescent (Borus & Laffel, 2010).

Health-related quality of life is a multidimensional concept that describes the social, physical, mental, and emotional well-being and reflects how the effects and treatment of diseases are perceived by the patient (Clarke & Eiser, 2004). The HRQoL was found to affect several life domains in adolescents with T1D including physical and social aspects, educational performance, and emotional well-being (Varni, Burwinkle, Jacobs, Gottschalk, Kaufman, & Jones, 2003). Studying HRQoL and associated factors in adolescents with T1D can provide more insight into their physical, psychological, and social needs which in turn would help in designing the appropriate regimen that fits with the expected clinical outcomes (Huang et al., 2004).

Compared to glycemic control, studies have shown that enhancing the HRQoL of adolescents with T1D is considered as a paramount factor in preventing diabetes complications and disease morbidities (Da Costa & Vieira, 2015). The literature indicates that the majority of studies on HRQoL in adolescents with T1D had been conducted in Australia and Western countries, and very few studies had been conducted in the Arab countries (Al-Hayek et al., 2014; Abdul-Rasoul et al., 2013). In Jordan, only one study has been conducted and reported low levels of HRQoL in Jordanian adolescents with T1D (Al-Akour, Khader, & Shatnawi 2010). While there is a clear difference in the cultural components, family structure, lifestyles, and healthcare systems between

different societies, it is important to study to which extent HRQoL may influence the management and clinical outcomes of T1D in such communities.

Physical activity is an important aspect of T1D management. According to ADA (2014) guidelines, children with T1D or pre-diabetes are recommended to perform at least one hour of regular PA on daily basis. Regular PA has been found to increase cardiovascular fitness, decrease body fat composition, decrease daily insulin doses, and improve the quality of life in patients with T1D (Chimen, Kennedy, Nirantharakumar, Pang, Andrews, & Narendran, 2012). Several observational studies found that lower prevalence, incidence, severity, and complications of T1D were associated with higher levels of PA in adolescents with T1D (Tielemans et al., 2013; Kennedy et al., 2013). In contrast, there is a clear lack of evidence on the effect of PA on the glycemic control in adolescents with T1D (Chimen et al., 2013; Kennedy et al., 2013). Some studies reported improvement in glycemic control with increased levels of daily PA in adolescents with T1D (Herbst, Bachran, Kapellen, & Holl, 2006), but others have not found an association (Aman et al., 2009; Galler, Lindau, Ernert, Thalemann, & Raile, 2011). Several studies that assessed PA in adolescents revealed that PA levels are sub-optimal (Aman et al., 2009; Kennedy et al., 2013; Overby et al., 2009) because of a fear of hypoglycemia or low levels of cardiorespiratory fitness (Wild et al., 2007). Therefore, it is important to examine the effect of PA on glycemic control and understand how cultural components may affect the rate of PA in Jordanian adolescents with T1D.

Finally, this study will provide an increased understanding of the influence of PA, HRQoL, and adherence on glycemic control in adolescents with T1D. Since cultural differences in family structure, lifestyle, food consumption, and physical and leisure

activities vary substantially between adolescents from different countries; studying Jordanian population will provide needed insight on how these factors could explain and influence on metabolic outcomes differently that, in turn, will enable researchers and clinicians to provide culturally-tailored interventions that promote and enhance these factors and positively improving clinical outcomes of this population.

Conceptual Framework

A conceptual framework for glycemic control in adolescents with T1D was developed by the primary researcher to serve as the theoretical model for this study (Figure 1). The framework illustrates glycemic control as an outcome of the positive contribution of three main variables: physical activity, health-related quality of life, and regimen adherence. Within this framework, the three predictors are interrelated and directly influence the glycemic status of adolescents with T1D. When considering variables that may influence adolescents' glycemic control, it is key to acknowledge the role of factors within adolescent's context that may influence the glycemic status such as age, gender, disease duration (length of time since diagnosis), and diabetes-related co-morbidities. These factors can directly or indirectly influence levels of physical activity the adolescents perform, their quality of life, and their ability to adhere to their therapeutic regimens.

Innovation

Poor glycemic control in adolescents with T1D can affect growth and expose adolescents to frequent episodes of hypoglycemia which can adversely impair neurological development. Furthermore, adolescents with T1D are generally more susceptible to the rapid development of diabetic ketoacidosis (DKA) than adults due to higher sensitivity to lack of insulin (Usher-Smith, Thompson, Ercole, & Walter, 2012).

Even in developed countries, there is clear epidemiological evidence that the mortality rates from DKA are significantly high in children and adolescents with T1D (Wolfsdorf et al., 2014). Given that T1D requires collaboration between the adolescent, the family, and healthcare providers; promoting PA, HRQoL, and adherence are likely to have a positive influence on glycemic control and clinical outcomes (Jaser et al., 2012). There is clear lack of studies on T1D in the Middle East (Memon et al., 2014). In Jordan, there are none published, as of August 2017, clinical studies that investigated the influence of HRQoL, PA, and adherence on glycemic control and subsequently the clinical outcomes in adolescents with T1D. Consequently, it becomes important to realize how controlled glycemic status of T1D patients influences quality of life, social competence, physical and cognitive development. Therefore, this study seeks to provide a better understanding of how PA, HRQoL, and regimen adherence impact glycemic control in this culturally unified population.

Approach

Research Design and Setting. The study will utilize a cross-sectional design to investigate the associations between PA, HRQoL, regimen adherence, and glycemic control. The participants will be Jordanian adolescents with T1D visiting the pediatric endocrinology clinic at King Abdullah University Hospital, a referral tertiary hospital located at north of Jordan. The study will commence when IRB approval is obtained and last until sample recruitment is complete.

Population, Sample and Sampling Procedures. The study sample will be Jordanian adolescents with T1D. Inclusion criteria for study participation are: (a) diagnosis of T1D >12 months; (b) age 12-18 years (c) have been a patient in the clinic over the course of at least one year and have at least 3 measurements of HbA1c; (d) free

of major mental health diagnosis; (e) able to read, write, and speak Arabic; and (f) willing to participate in the study and have parental consent. Participants will be excluded if they have a medical condition that interferes with physical activity recommendations. For a fixed-model multiple linear regression with three predictors, assuming an R^2 deviation from zero, a total sample size of 59 is required to achieve 80% power with a medium effect size of $F^2 = 0.20$ given the two-sided type I error of 5%. Given that a maximum of missing or incomplete data could be approximately 25%, the enrollment goal of the study is estimated to recruit 74 total subjects. A non-probability convenience sampling method will be used. Flyers for the study site will be posted to announce the study. The name and address of the investigator, a brief description of the study, the purpose of the study, method and duration of data collection, the contact person for further information, and a summary of inclusion criteria will be included.

Instruments

Demographic and medical history questionnaire. A structured questionnaire developed for the purpose of the study will be utilized to collect data on participants' age, gender, education level, parents' education, parents' employment, disease duration, body mass index, diabetes-related co-morbidities, and insulin regimen modality.

Health-Related Quality of Life. Health-related quality of life will be measured using the Arabic version of The Pediatric Quality of Life Inventory 3.0 Diabetes Module (PedsQL-MD), a culturally adapted version from the original instrument; The Pediatric Quality of Life Inventory (PedsQL). The PedsQL is a modeled-designed instrument used to measure HRQoL in children and adolescents aged 12-18 years (Varni, Burwinkle, Jacobs, Gottschalk, Kaufman & Jones, 2003). The PedsQL-MD Module was designed to measure diabetes-specific HRQoL in children and adolescents with T1D aged 12-18years

(Varni et al., 2003). The PedsQL-MD consists of 28 items with five subscales: Diabetes (11 items), Treatment I (4 items), Treatment II (7 items), Worry (3 items), and Communication (3 items). Respondents rate their responses on a 5-point Likert scale (*0 = never a problem, 4 = almost always a problem*). Data analysis will be performed following the "Scaling and Scoring of the Pediatric Quality of Life Inventory™ PedsQL" (Varni, 2014). To compute each score, all items will be reversed and linearly transformed to a 0-100 scale. The total score will be calculated by summing of all items divided by the number of answered items on the total scale. To account for missing data, the scale score will not be computed if more than 50% of the items are missing. The instrument has been previously used in Arabic-speaking children with T1D and has demonstrated satisfactory internal consistency reliability (Cronbach's alpha > 0.70) (Abdul-Rasoul et al., 2012). The required time to complete the instrument was evaluated and found to be 5-7 minutes with minimal missing responses indicating its feasibility.

Physical Activity. Physical activity will be measured using the official Arabic short-version of The International Physical Activity Questionnaire for Adolescents (IPAQ) which is publicly available atwww.ipaq.ki.se. The Arabic short form of the IPAQ has seven items and provides information on the PA intensity (vigorous, moderate, walking), duration (minutes per session), and frequency (days per week) during the preceding week. Two scoring protocols have been proposed by the IPAQ: categorical and continuous scoring. Categorical scoring suggests that respondents are to be categorized into one of three PA levels; high, moderate, or low using algorithms provided in the IPAQ scoring protocol (www.ipaq.ki.se). Continuous scoring suggests that PA levels to be expressed as metabolic equivalents (MET) per minute per week. The MET is a

physiological measure representing the energy cost of PA. One MET is defined as 1 kcal/kg/hour and considered equivalent to the energy expended by an individual while sitting. MET/minute/week will be calculated using the following equation: "MET level x minutes of activity x events per week". All continuous scores for vigorous, moderate and walking will be expressed as MET-minutes/week using the recommended values for each category as walking PA = 3.3 METs, moderate PA = 4.0 METs and vigorous PA = 8.0 METs. As suggested by Ainsworth et al. (2000), the following calculation method will be used to yield four continuous scores:

1. "Walking MET-minutes/week = 3.3 × walking minutes × walking days.
2. Moderate MET-minutes/week = 4.0 × moderate-intensity activity minutes × moderate days.
3. Vigorous MET-minutes/week = 8.0 × vigorous-intensity activity minutes × vigorous-intensity days.
4. Total physical activity MET-minutes/week = walking + moderate + vigorous MET-minutes/ week scores".

Data management and analysis for PA will be performed using the "Guidelines for Data Processing and Analysis of the IPAQ" (2005). The IPAQ was tested for reliability and validity in 12 countries during 2000 (Craig et al., 2003). The questionnaire demonstrated satisfactory stability of the instrument within the same week with Spearman's correlation coefficients = .80. Results on criterion validity showed moderate agreement between the IPAQ short-form and CSA accelerometers (Craig et al., 2003). Also, the instrument was tested for validity and reliability in a sample of 51 overweight and obese Tunisian adolescents. Evidence of test-retest reliability with 2-weeks interval

shows high levels of *ICC* (ranged from .73 to .95) indicating adequate stability of the instrument (Regaieg, Charfi, Yaich, Damak, & Abid, 2014). Results on convergent validity indicated a strong correlation between the IPAQ-A scores and pedometer step counts ($r = .66$, $p < .001$) (Regaieg et al., 2014).

Adherence. Adherence will be measured using the Arabic version of The Summary of Diabetes Self-Care Activities–Arabic (SDSCA-Arabic), a culturally validated version from the original instrument; The Summary of Diabetes Self-Care Activities (Toobert, Hampson & Glasgow, 2000). The instrument has been successfully adapted for adolescents aged 12 to 18 years with T1D (Toobert et al., 2000). The SDSCA-Arabic is an 8-item self-report scale validated to assess the frequency of diabetes self-care tasks in the preceding week. The scale has four subscales as follows: exercise (2 items); blood-glucose testing (2 items); general diet (2 items), and foot care (2 items). The scale measures the number of days (0-7) respondent perform each behavior with a total score ranges from 0-56 where higher scores indicate better adherence. The SDSCA-Arabic was validated in a sample of patients with type 2 diabetes (T2D); however, the author recommends that the instrument could be used in T1D patients as it covers the same domains of self-management activities recommended for T1D patients (K. A. AlJohani, personal communication, November 21, 2016). Psychometric properties of the instrument were evaluated in a sample of 243 patients with T2D in Saudi Arabia (AlJohani, Kendall, & Snider, 2016). Evidence of reliability includes Cronbach's alpha of .76, indicating internal consistency reliability, and test-retest ($r = .91$, $p < .001$) indicating adequate stability of the instrument (AlJohani et al., 2016).

Glycemic Control. HbA1c levels will be retrospectively obtained from the participants' medical record. Glycemic control will be determined by calculating the average of the last three HbA1c values over the preceding year.

Data Collection

Collaboration and coordination with the clinic staff will be established prior screening and recruitment. To begin recruitment, a support letter will be obtained from the designated clinic administrator, and then the researcher and a research assistant (Trained nursing student) will orient the clinic staff on the study aim, recruitment, and inclusion criteria. The clinic staff will identify eligible participants and inform the researcher and/or the nursing student to approach them for potential enrollment in the study if the patient and parents agree. The researcher and/or the nursing student will approach potential participants in the presence of their parents and explain the study purpose and the voluntary participation prior to their consent. Once consent is gained, a packet containing the demographic questionnaire, the Arabic version of the PedsQL-MD, the Arabic version of the IPAQ, and the SDSCA-Arabic questionnaires will be given to each participant. A brief description will be provided by the researcher and/or the nursing student to inform the participant and parents about the contents of each questionnaire. Participants will complete the study instruments using pencil and paper while waiting to in the clinic's lobby before or after their visit and will be advised to fill the questionnaires in a private room at the designated clinic. The required time to complete all instruments is estimated to be less than 20 minutes. Collected data will be entered by the researcher into a secure database and instruments' scoring will be computed according to each instrument manual.

Data Analysis

All data will be analyzed using the SPSS software (IBM SPSS Statistics, Version 25, 2018). Categorical variables will be presented in term of percentages and counts, and continuous variables will be presented in term of means and standard deviations (SD).

Aim 1: Examine the association between PA and glycemic control in Jordanian adolescents with T1D. *Hypothesis 1.1*: Adolescents having high PA levels would have a glycemic control ≤ 7.5% as measured by HbA1c, independent of age and disease duration. This hypothesis will be tested using Pearson product-moment correlation coefficient.

Aim 2: Evaluate HRQoL of Jordanian adolescents with T1D and examine gender and its association with glycemic control. *Hypothesis 2.1:* There are significant gender differences in adolescent HRQoL (specifically, girls have poorer self-rated HRQoL than boys), independent of age and disease duration. This hypothesis will be tested by using independent sample t-test to compare the means of HRQoL for females and males adolescents of the total sample and in each subgroup. *Hypothesis 2.2*: Adolescents having low HRQoL scores would exhibit high levels of glycemic control (HbA1c ≥ 9%), independent of age and disease duration. This hypothesis will be tested by using Pearson product-moment correlation coefficient.

Aim 3: Examine the association between regimen adherence and glycemic control in Jordanian adolescents with T1D. *Hypothesis 3.1*: Adolescents with high adherence scores would have a glycemic control ≤ 7.5% as measured by HbA1c, independent of age and disease duration. This hypothesis will be tested by using Pearson product-moment correlation coefficient.

Aim 4: Examine the interaction between PA, HRQoL, and adherence in the prediction of glycemic control in Jordanian adolescents with T1D. *Hypothesis 4.1*: The HRQoL will interact with adherence in the prediction of glycemic control with higher scores in both variables predict a glycemic control of ≤ 7.5% as measured by HbA1c. *Hypothesis 4.2*: The HRQoL will interact with PA in the prediction of glycemic control with higher scores in both variables predict a glycemic control of ≤ 7.5% as measured by HbA1c. *Hypothesis 4.3*: There will be no interaction between PA and adherence in the prediction of glycemic control in Jordanian adolescents with T1D. These three hypotheses will be tested using multiple linear regression tests. All regression models will be adjusted for age, gender, and disease duration. A *P* value of <.05 will be considered statistically significant in all of the analyses.

Study Limitations

There are several potential limitations in this study such as sampling technique and sample size. Participants will be recruited non-randomly which may yield a non-representative sample of the study population. The estimated sample size (*N*=74) is considered small, and it may be difficult to find significant correlations between the study variables. Since the primary researcher will retrieve the latest three readings of HbA1c for each participant, there may be some missing data which may limit the scope of our analysis. The utilization of a cross-sectional design will limit generalizability but this pilot study will help to inform future studies with larger samples using the information provided by this study.

Human Subjects

Permission to conduct the study will be obtained from the Institutional Review Board (IRB) of The University of Texas Health Science Center at Houston, and from the

IRB of King Abdullah University Hospital where the study will be conducted. Human subjects' procedures include the recruitment procedure, the eligibility screening process, completing the study questionnaires, and accessing the medical files to obtain the HbA1c values. The study will include both male and female adolescents with T1D.

After consent is obtained from adolescents and their parents, data collection will include gathering information from participants' medical records and questionnaires filling that will be used for research purposes only. Participants will be provided with information on the voluntary nature of participation, potential benefits, risks, and the use of the gathered information. In general, it is anticipated that the risks associated with enrollment in the study are of low risk. However, there is always a risk of a breach of confidentiality. All participants will be advised to fill the questionnaires in a private room at the designated clinic. IRB approval will be obtained prior to any communication with the participants. All participants will not be approached if their parents are not in attendance or unavailable. Participant's rights, needs, values, reputation, and confidentiality will be upheld by the researcher. Subjects who meet the inclusion criteria and willing to participate in the study will be given an informed consent to be signed by the adolescent and his/her parents. All participants will also be informed that if they no longer wish to participate for whatever reason, they could withdraw from the study at any time. Informed consent will be obtained from all adolescents and their parents, and the list of eligible subjects and completed data will be stored in a locked drawer cabinet free from potential breach. There are no direct benefits from participation in the study; however, findings of the study may help health care providers on national and international levels to better understand the influential role of PA, HRQoL, and

adherence on the glycemic control which may help them to provide better management and care.

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ASSOCIATIONS BETWEEN PHYSICAL ACTIVITY, HEALTH-RELATED QUALITY OF LIFE, REGIMEN ADHERENCE, AND GLYCEMIC CONTROL IN JORDANIAN ADOLESCENTS WITH TYPE 1 DIABETES

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIRMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

CIZIK SCHOOL OF NURSING

BY

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Abstract

Background: Adolescents with Type 1 Diabetes (T1D) display a greater than two-fold higher risk of developing microvascular and macrovascular complications compared with the non-diabetic population and the risk increases markedly as glycated hemoglobin (HbA1c) increases. The majority of the findings on the associated factors with improved glycemic control are geared toward Western population with a clear lack of studies on Middle Eastern populations. **Purpose:** This study aimed to examine the effect of Physical Activity (PA), Health-Related Quality of Life (HRQoL), and regimen adherence on glycemic control in Jordanian adolescents with T1D. **Methods:** The study utilized a cross-sectional design. Jordanian adolescents (aged 12-18) with T1D (n=74) were recruited. Self-reported measures were used including the Pediatric Quality of Life-Diabetes Module, the International Physical Activity Questionnaire, and the Summary of Diabetes Self-Care Activities. HbA1c values were obtained from the medical records. Correlation analyses were conducted using Pearson's and Spearman's correlation tests. Multiple regression analyses were conducted to determine if HRQoL, PA, and regimen adherence predict glycemic control. **Results:** Only 14.8% of the participants demonstrated good glycemic control (HbA1c $\leq$ 7.5%). Participants with poor control had a statistically significant lower mean PA of MET-minutes/week (3531.9 ± 1356.75 vs. 1619.81 ± 1481.95, $p < .001$) compared to those with good control. The total sample was found to demonstrate low HRQoL (47.70 ± 10.32). Participants were within the acceptable range of PA (1885.38 ±1601.13) MET-minutes/week. HbA1c significantly inversely correlated with PA ($r = -.328$, $p = .010$) and regimen adherence ($r = -.299$, $p = .018$). Regimen adherence and PA significantly predicted HbA1c in the unadjusted

regression model (β = -.367, p < .01; β = -.409, p < .01) and after adjustment for age and disease duration (β = -.360, p < .01; β = -.475, p < .01). In the interaction model, the interaction between PA and regimen adherence was statistically significant (β = -.304, p < .05). **Conclusion:** Better glycemic control was significantly predicted by higher PA and regimen adherence levels. There was no significant association between glycemic control and HRQoL. Further research is needed to provide more information on psychosocial and cultural factors that impact glycemic control and quality of life in this population.

Background

Type 1 diabetes (T1D) is an organ-specific autoimmune disease that occurs when the insulin-producing pancreatic beta cells are destroyed by the immune system, leading to a chronic deficiency of insulin hormone in genetically susceptible individuals. The insulin deficiency results in decreased insulin utilization and increased hepatic glucose production leading to hyperglycemia (Echeverri & Tobón, 2013). According to the American Diabetes Association (ADA) (2017), the diagnosis and classification of T1D is usually confirmed in symptomatic patients with a markedly raised random blood glucose finding of $\geq$ 200 mg/dl (11.1 mmol/L) accompanied by clinical symptoms of polydipsia, polyuria, weight loss, ketonuria , and marked hyperglycemia (Marathe, Gao, & Close, 2017). Once the diagnosis is confirmed, serum concentration of the glycated hemoglobin (HbA1c) level is used as a standard measure to assess therapeutic effectiveness and to determine how long a patient has had hyperglycemia (Marathe et al., 2017).

Type 1 diabetes is a serious illness associated with significant morbidity and mortality because of its both acute and long-term complications (Demirel, Tepe, Kara, & Esen, 2013). Diabetes-related macro and microvascular complications as cardiovascular diseases, retinopathy, and nephropathy are life-threatening problems with significant impacts on quality of life in children and adolescents with T1D (Demirel et al., 2013; Donaghue et al., 2014; Dabelea et al., 2017). Adolescents with T1D display a greater than two-fold higher risk of developing microvascular complications and cardiovascular disease compared with the non-diabetic population (Cho et al., 2011; De Ferranti et al., 2014) and the risk increases markedly as HbA1c increases (Virk et al., 2016). Despite the fact that the recommended level of HbA1c of less than 7.5% is generally associated with

decreased risk of diabetes-associated complications compared with higher levels, few adolescents with T1D achieved this target (Livingstone et al., 2012). Therefore, T1D treatment guidelines intensify controlled blood glucose levels and glycemic status to minimize the risk of macrovascular and microvascular complications (Cheng et al., 2013; Demirel et al., 2013). The recommended treatment regimen for T1D includes daily blood glucose measurement, daily insulin injections or using an insulin pump, monitoring and controlling carbohydrate intake, and performing physical activities (Marathe et al., 2017).

Globally there is a consistently increasing trend in the incidence of T1D (Egro, 2013) with a clear variation in the prevalence and incidence between countries (Maahs, West, Lawrence, & Mayer-Davis, 2010). For instance, about 1.25 million Americans are living with T1D including about 200,000 youth (less than 20 years old). The number is expected to increase 4 folds (5 million people) by 2050 including nearly 600,000 youth (Centers for Disease Control and Prevention, 2014). In the Arab world, there is clear epidemiological evidence that the incidence of T1D is high (Elhadd, Al-Amoudi, & Alzahrani, 2007), particularly in the Gulf region with large variations in the incidence, ranging from low in Oman (2.54/100,000) (Soliman, al-Salmi, & Asfour, 1996) to high in Saudi Arabia (29/100,000) (Habeb et al., 2011). Relatively, Jordan has a low incidence of T1D but the rate is increasing (Ajlouni, Khader, Batieha, & El-Khateeb, 2008).

Purpose Statement

Adolescence is a theoretical construct that is dynamically evolved through biological, psychological, and socio-cultural perspectives (Curtis, 2015). The chronological definition of adolescence describes the period as the years starting from puberty to the onset of social independence (Steinberg, 2014). Given the critical

developmental, emotional, cognitive, and social changes that occur during adolescence, the presence of a chronic condition during this period can lead to significant anxiety and stress that is associated with risk for emotional and behavioral problems that interferes with regimen adherence (Compas, Jaser, Dunn, & Rodriguez, 2012). If diabetes care is not executed well, adolescents with T1D can face both acute and chronic complications (Usher-Smith, Thompson, Ercole, & Walter, 2012).

Type 1 Diabetes and Glycemic Control

Glycated hemoglobin is a biometric index of the percentage of the three-month average plasma glucose concentration. The standardized HbA1c test is widely accepted and used to evaluate the glycemic control and diabetes care. According to the ADA Standards of Medical Care in Diabetes (2017), the target of HbA1c for adolescents with T1D is recommended to be below 7.5% (58 mmol/L) (Marathe et al., 2017). The benefits of maintaining stable and controlled glycemic status among T1D patients are well documented. Furthermore, the earlier the HbA1c level is lowered, the greater the benefits are optimized. The results from the Epidemiology of Diabetes Interventions and Complications (EDIC) study and the Diabetes Control and Complications Trial (DCCT) indicated that constantly increased HbA1c for 5-7 years during adolescence results in an increased risk for diabetes-related complications in the next 6 to 10 years on age (Steffes et al., 2003; Dovc et al., 2014).

Type 1 Diabetes and Physical Activity

Physical activity (PA) has been considered an essential component of the management of T1D. Physical activity is broadly defined as “as any movement of skeletal muscle that results in energy expenditure above resting levels, whereas exercise

is a subset of physical activity where the engagement of skeletal muscle in movement is planned, structured, repetitive, and for the purpose of training, fitness or developing a sports skill" (Annan, 2013, p. 234). When considering the role of exercise in T1D, it is important to understand that the insulin secretion is independent of counter-regulatory hormonal response during exercise; therefore, blood glucose regulation is not well controlled during exercise due to the complete absence of the physiological suppression of insulin which leads to inadequate muscular uptake of glucose. Therefore PA in children and adolescents with T1D may induce hyperglycemia and hypoglycemia events during and after exercise (Iughetti, Gavioli, Bonetti, & Predieri, 2015). Hence, several factors must be considered when planning PA for children and adolescents with T1D including type, duration, intensity, and timing of the exercise, number of muscles used in the exercise, glycemic control, frequency of insulin injections, type of food, frequency of daily meals, and blood glucose level (Robertson et al., 2015).

For instance, the type of exercise such as aerobic and resistance training exercises can contribute to a wide range of blood glucose responses (Turner et al., 2016). Exercise duration also has a vital impact on blood glucose outcomes in patients with T1D, with longer durations generally resulting in greater risk of hypoglycemia during and after exercise (Turner et al., 2015). Therefore, balancing all of these variables can be predominately challenging for children and adolescents with T1D who choose to be more active to avoid exercise-induced complications (Brazeau, Rabasa-Lhoret, Strychar, & Mircescu, 2008).

The ADA (2017) guidelines indicates that children and adolescents with T1D perform at least one hour of moderate-vigorous physical activity (MVPA) on daily basis.

These general guidelines are directed toward a combined form of PA including moderate and vigorous activities that enhance the cardiovascular, musculoskeletal, and metabolic functionality (Pivovarov, Taplin, & Riddell, 2015). In T1D adolescents with good glycemic control, regular PA has been found to increase cardiovascular fitness, reduce cardiovascular risk factors, decrease daily insulin doses, and enhance psychosocial well-being (Chimen, Kennedy, Nirantharakumar, Pang, Andrews, & Narendran, 2012). Despite the associated benefits, adolescents with T1D were commonly reported to be less active compared with non-diabetic peers which contribute to macrovascular and microvascular risks (Lukacs, Mayer, Juhasz, Varga, Fodor, & Barkai, 2012; Leroux, Brazeau, Gingras, Desjardins, Strychar, & Rabasa-Lhoret, 2014). Several observational studies found that the lower prevalence, incidence, severity, and complications of T1D in adolescents were associated with higher levels of PA (Tielemans et al., 2013; Kennedy et al., 2013).

The evidence for the effect of PA on glycemic control is ambiguous. For instance, some studies reported improvement in glycemic control with increased levels of daily PA in adolescents with T1D (Schweiger, Klingensmith, & Snell-Bergeon, 2010), but others have not found any association (Aman et al., 2009; Galler, Lindau, Ernert, Thalemann, & Raile, 2011). Several other studies found an inverse correlation between PA and HbA1c levels (Herbst et al., 2007; Herbst, Bachran, Kapellen, & Holl, 2006). Similarly, several meta-analyses reported contradictory results. While Quirk and colleagues (2014) suggested an improvement in the glycemic status of physically active adolescents with T1D, Kennedy and colleagues (2013) did not find any association between glycemic control and PA in adolescents with T1D.

Type 1 Diabetes and Health-Related Quality of Life

Health-Related Quality of Life (HRQoL) is a multidimensional concept that describes the social, physical, mental, and emotional well-being and reflects how the effects and treatment of diseases are perceived (Clarke & Eiser, 2004). According to the International Society for Pediatric and Adolescent Diabetes (ISPAD) clinical practice consensus guidelines (2014), evaluation of HRQoL is considered an essential component in order to determine disease progression and type of insulin regimen that would be efficient to maintain the recommended glycemic control with decreased impact on HRQoL (Delamater et al., 2014). Enhancing the HRQoL of adolescents with T1D has been suggested to be a paramount factor in preventing diabetes complications and disease morbidities (Da Costa & Vieira, 2015).While the care of T1D requires high levels of shared responsibilities and self-control to achieve the recommended glycemic control, several studies reported that children and adolescents who are of older age, living with a single parent, and lower family income exhibit poor glycemic control and worse HRQoL (Delamater et al., 2014; Özyazıcıoğlu, Avdal, & Sağlam, 2017).

Type 1 Diabetes and Regimen Adherence

Only 21% of adolescents with T1D were reported to meet the ADA guidelines for the recommended HbA1c level in the United States of America (USA) (Wood et al., 2013). The association between regimen adherence and glycemic control suggests that regimen adherence must be maximized in order to control glycemic status (Hood, Peterson, Rohan & Drotar, 2009). Furthermore, regimen adherence and glycemic control are known to substantially deteriorate during adolescence (Rausch et al., 2012).

Regimen adherence is broadly defined as "the degree to which patients follow the recommendations of their health professionals" (Kelly & DiMatteo, 2009, p.826). In patients with T1D, these recommendations include measuring blood glucose four to six times per day, regulating carbohydrates intake, taking insulin therapy as needed, performing physical exercises, and attending routine clinic appointments (ADA, 2017). Considering technologic advancement in diabetes management, data indicate that adherence to therapy challenges even the most competent and motivated adolescent and continues to be a problem (Borus & Laffel, 2010). For example, data from a large cross-sectional study (N= 17,317) indicated that using new diabetes care technologies such as continuous blood glucose monitoring was associated with lower HbA1c (8.3% vs. 8.6%, p <.001), however, participants rarely used the technology to measure and report their daily blood glucose (Wong et al., 2014). Furthermore, the findings from a meta-analysis of 21 studies included 2,429 adolescents with T1D supported that better treatment adherence predicts improved glycemic control independent of demographic factors such as race, ethnicity, income, and single parenthood (Hood et al., 2009). In contrast, adolescents who demonstrated better adherence have better glycemic control and fewer diabetes complications compared with adolescents who less frequently engaged in adherence behaviors (Patton, 2015). Therefore, these findings reinforce the fact that regimen adherence is a core prerequisite to improve glycemic control in adolescents with T1D.

Statement of the Problem

Macrovascular and microvascular complications remain the major cause of morbidity and mortality in patients with T1D (You & Henneberg, 2016). Considering the

efforts made by many well-established agencies such as the World Health Organization (WHO), the International Society for Pediatric and Adolescent Diabetes (ISPAD), and the American Diabetes Association (ADA), through establishing, updating, and publishing treatment guidelines, and recommending which treatment protocol is more effective for T1D patients, implementation and utilization of these protocols still underestimations.

Poor glycemic control in adolescents with T1D can affect growth and expose adolescents to frequent episodes of hypoglycemia which can adversely impair neurological development (Usher-Smith et al., 2012). Additionally, there are relatively sufficient information in the literature on various demographic and clinical factors that are reported to be predictors of glycemic control such as age, gender, disease duration (Clements et al., 2014; Åkesson et al., 2015; Esdonk, Tai, Cotterill, Charles, & Hennig, 2017), body mass index (BMI) (Bae, Lage, Mo, Nelson, & Hoogwerf, 2016; Vaid, Hanks, Griffin, & Ashraf, 2016), insulin requirements (Beato-Víbora & Tormo-García, 2014), and carbohydrates counting (Bell, Barclay, Petocz, Colagiuri, & Brand-Miller, 2014). In contrast, information on the psychosocial, physical, and emotional factors that may affect glycemic control is not well studied and the available findings are controversial. Furthermore, the traditional concept of relying heavily on pharmacological components to minimize and prevent medical complications has been shifted to emphasize the importance of including all health dimensions including social, psychological, and emotional components of patients' life. Therefore, it is vitally important to gear research toward investigating other factors that may influence glycemic

control and consequently improve the quality of life and clinical outcome in the T1D adolescent population.

Furthermore, adolescents with T1D are clearly understudied in the Middle East and particularly in Jordan, with only one study conducted in 2010 that reported low levels of HRQoL in Jordanian adolescents with T1D (Al-Akour, Khader & Shatnawi, 2010). The majority of research on adolescents with T1D has been conducted in Westren counries. Given the differences in health care delivery systems, lifestyles, religion, cultural components, and family structure and dynamics in different countries, the findings of these existing studies may not be generalizable to Middle Eastern adolescents. Therefore, it is important to study the influence of PA, HRQoL, and regimen adherence on the glycemic control and subsequently the clinical outcomes in this population.

Purpose

The purpose of this cross-sectional study was to examine the effect of PA, HRQoL, and regimen adherence on glycemic control in Jordanian adolescents (aged 12-18) with T1D. Since cultural differences in family structure and lifestyle fundamentally vary between adolescents from different countries, the findings of this study were intended to provide needed insight on how these factors could explain and influence on metabolic outcomes differently, that in turn will enable researchers and clinicians to provide culturally-tailored interventions that promote and enhance these factors thereby positively improve clinical outcomes of this culturally unified population.

Specific Aims and Hypotheses

The specific aims and hypotheses were:

1) Examine the association between PA and glycemic control in Jordanian adolescents with T1D.

It was hypothesized that PA would negatively correlate with glycemic control, and adolescents having high PA levels would have a glycemic control ≤ 7.5% as measured by HbA1c, independent of age and disease duration.

2) Evaluate HRQoL of Jordanian adolescents with T1D and examine gender and its association with glycemic control.

It was hypothesized that HRQoL would negatively correlate with glycemic control, and adolescents having low HRQoL scores would exhibit high levels of glycemic control (HbA1c ≥ 9%), independent of age.

3) Examine the association between regimen adherence and glycemic control in Jordanian adolescents with T1D.

It was hypothesized that regimen adherence would negatively correlate with glycemic control, and adolescents with high adherence scores would have a glycemic control ≤ 7.5% as measured by HbA1c, independent of age and disease duration.

4) Examine the interaction between PA, HRQoL, and regimen adherence in the prediction of glycemic control in Jordanian adolescents with T1D.

It was hypothesized that HRQoL will interact with adherence in the prediction of glycemic control with higher scores in both variables predict a glycemic control of ≤ 7.5% as measured by HbA1c. Also, the HRQoL will interact with PA in the prediction of glycemic control with higher scores in both variables predict a glycemic control of ≤ 7.5% as measured by HbA1c. Finally, there will be no interaction between PA and adherence in the prediction of glycemic control.

Conceptual Framework

A conceptual framework for glycemic control in adolescents with T1D was developed by the authors to serve as the theoretical model for the study. The framework is shown in Figure 1. The framework illustrates glycemic control as an outcome of the positive contribution of three main variables: physical activity, health-related quality of life, and regimen adherence. Within this framework, the three predictors are interrelated and directly influence the glycemic status of adolescents with T1D. When considering variables that may influence adolescents' glycemic control, it is key to acknowledge the role of factors within adolescent's context that may influence the glycemic status such as age, gender, disease duration (length of time since diagnosis), and diabetes-related co-morbidities. These factors can directly or indirectly influence levels of physical activity the adolescents perform, their quality of life, and their ability to adhere to their therapeutic regimens.

Methods

This study utilized a cross-sectional research design. Self-report questionnaires were used to collect data on PA, HRQoL, and adherence from adolescents with T1D. The study was conducted at King Abdullah University Hospital (KAUH), a referral tertiary hospital located in the northern part of Jordan. The study was completed under the supervision of faculty at the University of Texas Health Science Center at Houston, Cizik School of Nursing. The study was granted full Institutional Review Board (IRB) approval from both institutions (Appendix A & Appendix B).

Participants

Participants were 12-18-year-old Jordanian adolescents with T1D who visited a pediatric endocrinologist at two pediatric diabetes clinics between November 4, 2017, and January 11, 2018. Inclusion criteria for the study were as follows: (a) diagnosis of T1D >12 months; (b) age 12-18 years (c) have at least 3 measurements of HbA1c; (d) free of major mental health diagnosis; (e) able to read, write, and speak Arabic; and (f) willing to participate in the study and have parental consent. Subjects suffering from any medical condition that interferes with physical activity recommendations were excluded.

To calculate the sample size, a power analysis was conducted using G*Power software (Version 3.1.9.2). For a fixed-model multiple linear regression with three predictors, assuming an R^2 deviation from zero, a total sample size of 59 was required to achieve 80% power with a medium effect size of $F^2 = 0.20$ given the two-sided type I error of 5%. Given that a maximum of missing or incomplete data could be approximately 25%, the enrollment goal of the study was estimated to recruit 74 total subjects.

A total of 119 participants and their parents were approached and invited to participate, and 108 agreed to do so. Of the 108 participants, 74 were eligible and thus comprised the sample size in the study. Thirty-four potential subjects were excluded for several reasons including missing data (i.e. complete absence of HbA1c data) (n=12), being younger than 12-year-old (n=16), have been diagnosed with T1D for less than 1 year (n=5), and having a medical condition that interferes with physical activity recommendations (n=1). The study sample was collected using a nonprobability convenience sampling technique.

Procedure

Following IRB approvals, study flyers (Appendix C & Appendix D) were posted to announce the study. Prior to recruitment, a support letter from the designated clinic's administrations was obtained followed by a brief orientation on the study aim, recruitment, and inclusion criteria. While waiting to be seen by their physician, potential participants were approached by the researcher and invited to participate in the study in the presence of their parents or guardians. If parents and the adolescent agreed, screening for eligibility was done by the researcher and a trained nursing student. After informed consent was signed by the participant, his/her parents, and a witness (Appendix E & Appendix F), the researcher disseminated the study questionnaires. Selected participants and their parents were asked to complete the study questionnaires in the waiting room of the clinic. The researcher and/or the nursing student remained with the participants to answer any questions or comments. Once finished, the researcher and/or the nursing student checked that all items had been answered.

Participants' medical records were used to obtain the following information: HbA1c, height, weight, body mass index, and disease duration. At least one HbA1c value over the last year period was obtained from the participants' medical records for study inclusion. However, due to the large time difference between the participants in the date of the recent HbA1c value, a decision was made that participants with two HbA1c values (n=62) were considered in the final analyses using the average of the two values.

All participants' data were kept confidential. Hence, no personal identification was recorded and each questionnaires packet was given a unique identification number. Participants voluntarily participated in the study with the right to withdraw at any time.

The presented findings were derived from participants who completed all questionnaires and had at least one HbA1c value. Completed data were entered into a password-protected statistical software program stored on the researcher's locked laptop.

Measures and Instruments

The Pediatric Quality of Life Inventory 3.0 Diabetes Module (PedsQL-MD).

The PedsQL-MD Arabic version (Appendix G) is a culturally adapted version of the original instrument, The Pediatric Quality of Life Inventory (PedsQL) (Appendix H). The PedsQL is a modeled-designed instrument used to measure HRQoL in children and adolescents aged 12-18 years (Varni, Burwinkle, Jacobs, Gottschalk, Kaufman, & Jones, 2003).The PedsQL-MD was designed to measure diabetes-specific HRQoL in children and adolescents with T1D aged 12-18years (Varni et al., 2003). The PedsQL-MD consists of 28 items with five subscales: Diabetes Symptoms (11 items), Treatment Barriers (4 items), Treatment Adherence (7 items), Worry (3 items), and Communication (3 items). Respondents rated their responses on a 5-point Likert scale (*0 = never a problem, 4 = almost always a problem*). The scale is available in two forms: the "child proxy" and the "parent proxy". Both proxies were completed by adolescent and/or parent respectively. In this study, the two forms are typically similar to the parent proxy providing a measure of adolescents' HRQoL from the view of the parent or caregiver (Varni et al., 2003). User agreement with the distribution agency was signed prior using the instrument.

The original version was tested for internal consistency reliability with Cronbach's alpha statistics. The instrument has been previously used in Arabic-speaking children with T1D and has demonstrated satisfactory internal consistency reliability

(Cronbach's alpha > .70) (Abdul-Rasoul, AlOtaibi, AlMahdi, & AlKandari, 2012). Construct validity of the Arabic version of the instrument was evaluated by examining the agreement between subscales in the PedsQL Generic Core Score (GCS) and the subscales in the PedsQL-MD using the interclass correlation coefficient (ICC) test. The results indicated that the subscales of both instruments sufficiently correlated with their total scale (*ICC* =.81) (Abdul-Rasoul et al., 2012).

In this study, scoring was performed using the "Scaling and Scoring of the Pediatric Quality of Life Inventory™ PedsQL" (Varni, 2014). To compute each score, all items were reversed and linearly transformed to a 0-100 scale. The total score was then calculated by summing of all items divided by the number of answered items on the total scale with higher scores indicating better HRQoL or fewer disease symptoms or problems. To account for missing data, the scale score was not computed if more than 50% of the items were missing. No missing data were detected in this study.

The International Physical Activity Questionnaire for Adolescents (IPAQ-A). The IPAQ-A (Appendix I) is a publicly available instrument used to measure PA in adolescents. To measure PA in the study population, the official Arabic short form of the IPAQ-A was adopted and used in this study (Appendix J). The instrument has seven items and provides information on the PA intensity (vigorous, moderate, walking), duration (minutes per session), and frequency (days per week) during the preceding week. Two scoring protocols have been proposed by the IPAQ: categorical and continuous scoring. Categorical scoring suggests that respondents are to be categorized into one of three PA levels; high, moderate, or low using algorithms provided in the IPAQ scoring protocol (www.ipaq.ki.se). Continuous scoring suggests that PA levels be

expressed as metabolic equivalents (MET) per minute per week. The MET is a physiological measure representing the energy expenditure of PA. One MET is defined as 1 kcal/kg/hour and considered equivalent to the energy consumed by an individual while sitting. For the purpose of this study, the continuous scoring protocol was implemented.

The metabolic equivalents (MET/minute/week) for each participant were calculated using the following equation: "MET level x minutes of activity x events per week". All continuous scores for vigorous, moderate and walking were computed and expressed as MET-minutes/week using the recommended values for each category as: walking PA = 3.3 METs, moderate PA = 4.0 METs and vigorous PA = 8.0 METs. As suggested by Ainsworth et al. (2000), the following calculation methods were used and yielded four continuous scores: "(1) Walking MET-minutes/week = 3.3 × walking minutes × walking days, (2) Moderate MET-minutes/week = 4.0 × moderate-intensity activity minutes × moderate days, (3) Vigorous MET-minutes/week = 8.0 × vigorous-intensity activity minutes × vigorous-intensity days, (4) Total physical activity MET-minutes/week = walking + moderate + vigorous MET-minutes/ week scores".

Each category of PA (i.e. vigorous, moderate, walking) is represented by two questions; one on the duration and one on the frequency. The seventh question in the IPAQ is the sitting question, an additional indicator sedentary behavior (sitting) in the last preceding week. As per the scoring criteria, the sitting question is not to be considered in calculating any of the PA categories. To date, there are no well-accepted thresholds on sedentary behaviors to be presented as categorical level. Therefore, the score in this question was used as a continuous variable in the subsequent analyses. According to the American College of Sports Medicine and the American Heart Association

recommendations, the acceptable range to get the health benefits of PA is 500 to 1,000 MET-minutes per week (Nelson et al., 2007).

Data management and analysis for PA were performed using the "Guidelines for Data Processing and Analysis of the IPAQ" (2005). The IPAQ was tested for reliability and validity in 12 countries during 2000 (Craig et al., 2003). The questionnaire demonstrated satisfactory stability of the instrument within the same week with Spearman's correlation coefficients = .80. Results on criterion validity showed moderate agreement between the IPAQ short-form and CSA accelerometers (Craig et al., 2003). Also, the instrument was tested for validity and reliability in a sample of 51 overweight and obese Arabic speaking Tunisian adolescents. Evidence of test-retest reliability with 2-weeks interval shows high levels of ICC (*ICC* =.73 - .95) indicating adequate stability of the instrument (Regaieg, Charfi, Yaich, Damak, & Abid, 2014). Results on convergent validity indicated a strong correlation between the IPAQ-A scores and pedometer step counts (r =.66, p <. 001) (Regaieg et al., 2014).

The Summary of Diabetes Self-Care Activities–Arabic (SDSCA-Arabic). The Arabic version of the SDSCA-Arabic (Appendix K) is a culturally validated version from the original instrument and has been successfully adapted for patients with type 1 and type 2 diabetes mellitus (AlJohani, Kendall & Snider, 2016). The original instrument, The Summary of Diabetes Self-Care Activities (Appendix L), has been successfully adapted for adolescents aged 12 to 18 years with T1D (Toobert, Hampson & Glasgow, 2000). The SDSCA-Arabic is an 8-item self-report scale validated to assess the frequency of diabetes self-care tasks in the preceding week. The scale has four subscales as follows: exercise (2 items); blood-glucose testing (2 items); general diet (2 items), and foot care (2

items). The scale measures the number of days (0-7) respondent perform each behavior with a total range from 0-56 where higher scores indicate better adherence. The SDSCA-Arabic was validated on a sample of patients with type 2 diabetes (T2D); however, the author recommends that the instrument could be used in T1D patients as it covers the same domains of self-management activities recommended for T1D patients (K. A. AlJohani, personal communication, November 21, 2016). Psychometric properties of the instrument were evaluated in a sample of 243 patients with T2D in Saudi Arabia (AlJohani et al., 2016). Evidence of reliability includes Cronbach's alpha of .76, indicating internal consistency reliability, and test-retest (r =.912, p < .001) indicating adequate stability of the instrument (AlJohani et al., 2016).

Glycemic Control. Glycemic control was measured by HbA1c levels. Values were obtained retrospectively from the participants' medical records at time of participant clinic visit using a data sheet developed for the purpose of this study (Appendix M). For greater stability and consistency across the sample, participants' HbA1c values were averaged across the most recent two values over the preceding year. The ADA (2017) recommends HbA1c levels for adolescents to be below 7.5%. High HbA1c levels were indicated as poor glycemic control.

Demographic and Clinical Information Questionnaire. Participants' demographic and clinical information were collected using a structured questionnaire developed for the purpose of the study and completed by the adolescents' and/or their parents (Appendix N & Appendix O). Data were collected about participants' age, gender, education level, parents marital status, parenthood, father education, father employment, mother education, mother employment, health insurance, disease duration,

age at diagnosis, family history of diabetes, BMI, diabetes-related co-morbidities, mode of insulin delivery, number of daily injections, frequency of daily blood glucose measurement, number of hospitalizations due to diabetes last year, and episodes of reported hypoglycemia last month.

Statistical Analysis

Statistical analyses were performed by the researcher using the Statistical Package for the Social Sciences (SPSS-IBM) computer software, version 25.0 (SPSS Inc., Chicago, IL, USA). Initially, univariate outliers and violation of statistical assumptions were checked prior to analysis. To assess for univariate outliers, all variables were standardized and the *Z*-scores were computed. From a statistical point of view, the empirical rule indicates that 99.7% of the data must fall within three standard deviations from the mean (Shiffler, 1988). Therefore, a decision was made that any *Z*-score less than -3 or greater than 3 is considered as an outlier and removed from the analyses. Further, visualization of the outliers was done through computing the boxplot for each variable. Univariate normality was assessed with skewness and kurtosis. Variable transformation was considered if skewness or kurtosis values greater than 1.5. In the regression analysis, multicollinearity was examined with the Variance Inflation Factor (VIF), a statistical test that measures the effect of collinearity among the regression variables. Values of VIF that exceeded 10 were regarded as indication of multicollinearity. Also, homoscedasticity and linearity between the dependent and independent variables were assessed through visualization of the residuals scatterplot for each regression model.

Descriptive statistics were reported for the total sample (N=74). Mean, standard deviation (*SD*), 95% confidence interval (*IC*) for mean, median, and range were reported

for continuous variables. As well, frequency and percentage were reported for categorical variables. For greater stability, each participant's HbA1c data were reviewed to verify at least two values in the preceding year. If this criterion was not met, the participant was excluded from the correlation and regression analyses. The average of two values was then calculated and used as an indicator of glycemic control. Independent samples Student's *t*-tests were used to examine the mean difference in total HRQoL scores, total PA scores, total regimen adherence scores, and sedentary PA between males and females.

The strength of correlation between the dependent variable (HbA1c) and the three main independent variables (PA, HRQoL, regimen adherence) was examined using Pearson product-moment correlation coefficient at two-tailed significance level. The strength of correlation was also examined between demographic and clinical variables and HbA1c using Pearson product-moment correlation coefficient for normally distributed continuous variables (age, disease duration, BMI), and Spearman's Rank-Order correlation coefficient for categorical, non-normally distributed variables (education level, father education, mother education, father employment, mother employment).

A multiple linear regression model was performed with averaged HbA1c as the dependent variable, and PA, HRQoL, and regimen adherence as the independent variables. According to Aiken & West (1991), all analyses were performed on the standardized z-scores. The first model included only the main effects of the three predictors. A second model was run and adjusted for age and disease duration. To test the effect of interaction, a third model was conducted including the main effects of the three predictors (PA HRQoL, regimen adherence), the adjusted variables (age, disease

duration), as well as the interaction between PA and HRQoL, the interaction between PA and regimen adherence, and the interaction between HRQoL and regimen adherence. Variance Inflation Factor was implied to examine multicollinearity between the dependent variable and independent variables in each model. The significant change in *F-test* (<.05) and the model R^2were used in model selection and to assess the overall goodness of fit for each model. A *p* value of <.05 was used as an indicator of statistical significance in all of the analyses.

Results

Demographics and Clinical Characteristics

Of the 119 participants/parents approached, 108 (90.7%) agreed to participate in the study. Of those agreed, 74 (68.5%) were eligible and thus comprised the sample size in the study. Results on participants' demographics and clinical characteristics included data from the total sample (*N*=74). Summary of participants' demographics are shown in Table 1. Data are presented in mean (±*SD*).The mean age of the participants was 14.15 (± 1.55) years. The sample was primarily female (61%), 6th -10th school grader (79.7%), and living with both parents (94.6%). The parents were married in most of the cases (95.9%) and divorced in 4.1%. Thirty-eight percent of fathers and 43.2% of mothers reported education at college or university level. More than half the parents (62.1% of the fathers and 56.7% of the mothers) reported education at high school or less. Full-time employment was reported by 68.9% of the fathers and 10.8% of the mothers. The majority of the mothers (81.1%) were unemployed, whereas only 6.8% of fathers reported unemployment status.

Clinical characteristics of participants are presented in Table 2. All participants reported receiving insulin treatment with daily insulin injections with a mean of 2.76 (± .65) injections per day across the entire sample. Mean age at diabetes onset was 8.99 (± 1.97) years and mean disease duration since diagnosis with T1D was 5.15 (± 2.44) years. The frequency of blood glucose measurement was reported at a mean of 2.51 (± .78) measurements per day.

Hospitalization due to diabetes in the preceding year was also reported with a mean of 1.38 (± 1.10) admissions in the entire sample. The median number of hypoglycemic episodes in the preceding month was 2.6(range = 6) episodes. According to the calculated BMI, 15 (20.3%) participants were underweight, 36 (48.6%) were normal weight, and 23 (31.1%) were either overweight or obese. The overall mean of participants' BMI was 2.47 (± 1.68).

Descriptive statistics of glycemic control, PA, HRQoL, and regimen adherence are presented in Table 3. Overall, the mean percentage of HbA1c was 10.6 (± 2.81) indicating poor glycemic control among the total sample with slightly higher values in males (10.47 ± 2.68) than females (9.80 ± 2.89). Stratification of participants according to the HbA1c was done where participants with values of ≤ 7.5 were categorized as having good glycemic control and those with values > 7.5% were categorized as being in poor glycemic control. The results showed that only 11 (14.7%) participants demonstrated good glycemic control (HbA1c ≤ 7.5%) with no statistically significant difference in age and disease duration compared with participants with poor glycemic control. Participants with poor control had a statistically significant lower mean PA of

MET-minutes/week (3531.9 ± 1356.75 vs. 1619.81 ± 1481.95, p <.001) compared with good control.

The total sample was found to demonstrate below-average HRQoL with a mean total score of 47.70 (± 10.32). Female adolescents with T1D reported slightly higher total HRQoL (49.55 ± 10.50) than males (44.38 ± 9.52). Among the entire sample, the HRQoL scores were lower for diabetes symptoms (38.31 ± 20.37) and worry (25.62 ± 25.28) domains, and higher for communication (64.92 ± 23.11) domain.

Participants were within the acceptable range of PA with a mean of 1946.3 (±1321.91) MET-minutes per week for males and 1848.8 (±1760.82) MET-minutes per week for females (Nelson et al., 2007). Only 23 (31%) participants (10 males and 13 females) reported performing vigorous PA in the last 7 days with means of 2496 and 1115 MET-minutes per week respectively, and 67 (90.54%) reported performing moderate PA in the last 7 days with means of 831 and 674 MET-minutes per week respectively. The mean MET-minutes per week of walking was 937.42 (± 697.58) in males and 954.36 (± 880.36) in females. Regarding regimen adherence, the mean total score was 38.09.36 (± 8.86) for the entire sample with slightly higher in males than females (39.44 ± 7.84 vs. 37.22 ± 9.16).

Bivariate and Multivariate Analyses

All univariate and multivariate analyses were performed on the 62 participants who met the criterion of having at least two HbA1c values. To account for normality, all analyses were performed on the standardized z-scores. Outliers were detected and removed (n=2 in PA scores) from the analyses.

Independent samples Student's *t-tests* were performed to compare the means between males and females on HbA1c, HRQoL, PA, regimen adherence, and sedentary PA. The analysis showed that there was no statistically significant mean difference between males and females in HbA1c, HRQoL, PA, regimen adherence, and sedentary PA (Table 4).

To determine the relationships between HRQoL, PA, regimen adherence, clinical characteristics, and glycemic control, a Pearson product-moment correlation coefficient analysis was performed. The data were assessed for violation of statistical assumptions prior to analysis. Each variable was measured on a continuous scale, significant outliers were detected and removed, and normality was ascertained by using the standardized z-scores. The results are presented in Table 5. The analysis indicated a moderate, inverse correlation between PA and glycemic control as measured by HbA1c, which was statistically significant (r = -.328, n = 60, p = .010). Correspondingly, there was a moderate, positive correlation between sedentary PA and glycemic control as measured by HbA1c, which was statistically significant (r = .337, n = 60, p = .009). However, the analysis indicated a marginally moderate, inverse correlation between regimen adherence and HbA1c, which was statistically significant (r = -.299, n = 62, p = .018), this association did not appear in the subsequent multiple regression analyses. Further, there was no statistically significant association between glycemic control and HRQoL. There was also no statistically significant association between glycemic control and any of the clinical characteristics (including age), except for number of hypoglycemic episodes which was moderate and negative (r= -.371, n = 62, p = .003).

A Spearman's Rank-Order correlation analysis was conducted to determine the relationship between glycemic control and categorical, non-normally distributed variables including education level, father education, mother education, father employment, and mother employment. There was no any statistically significant correlation between glycemic control and any of the tested variables (Table 6).

To determine if HRQoL, PA, and regimen adherence predicts adolescents' glycemic control while adjusting for age and disease duration, three multiple regression analyses were conducted. The data were assessed for violation of statistical assumptions prior to analysis. Significant outliers were detected and removed (n=2 in PA scores). Assumptions on homoscedasticity and multicollinearity were assessed through plotting the studentized residuals against the unstandardized predicted values. To account for normality, regression analyses were conducted using the standardized *Z*-scores. The three models are presented in Table 7. In the first unadjusted, main-effects model, HbA1c was regressed with HRQoL, PA, and regimen adherence as predictors. The model was statistically significant and explained 22.8% of the variance in glycemic control ($F(3, 56)= 5.523$, $p <.01$, $R^2 = .228$). It was found that PA significantly predicted glycemic control ($\beta = -.367$, $p < .01$) as adherence did ($\beta = -.409$, $p < .01$). The regression coefficient associated with PA suggesting that for each one standardized unit increase in PA is associated with a .367 unite decrease in HbA1c. Also, an increase of one standardized unite in regimen adherence is associated with a .409 unite decrease in HbA1c. After adjustment for age and disease duration in the second model, PA and regimen adherence remained statistically significantly associated with the prediction of glycemic control and the magnitude of association was nearly the same for PA ($\beta = -.360$,

p <.01) and increased by 6.6% for regimen adherence (β = -.475, p <.01). It is suggested that a one unit increase in PA is associated with a .36 unite decrease in HbA1c holding age and disease duration constant. Interestingly, disease duration appeared to be significantly predictive of glycemic control (β= .444, p <.01) suggesting that each additional year in disease duration is associated with a .444 unit increase in HbA1c holding other variables constant in the model. The adjusted model was statistically significant and increased the amount of explained variance by 9.4% (F(2, 54)= 3.726, p <.05, R^2 = .322).

The final regression model was run including the unadjusted main-effects variables, the adjusted variables (age and disease duration), and the interaction terms between PA and HRQoL, PA and regimen adherence, and HRQoL and regimen adherence. The interaction model improved significantly and explained 43.4% of the variance in HbA1c (F(8, 51)= 4.883, p < .05, R^2 = .434). Both PA and regimen adherence remained statistically significant in the interaction model (β = -.488, p <.001, β = -.373, p <.01 respectively). None of the interaction terms was statistically significant except for the interaction between PA and regimen adherence (β = -.304, p <.05).

As described by Aiken & West (1991); when an interaction effect is present, the impact of one predictor depends on the level of the other predictor. In order to interpret the interaction effect in the regression model, regimen adherence was transformed into three categories as low (scores between 0-30), moderate (scores between 31-45), and high (scores between 46-56), then a scatterplot with a regression fit line was generated with PA as a combined variable and glycemic control as a dependent variable. The interaction between PA and regimen adherence is graphed using regression lines in Figure 2.

Correlations were calculated by taking the square root of R^2 linear values. As shown on the graph, the correlation between PA and HbA1c is .62 for adolescents with high regimen adherence level, .57 for adolescents with moderate regimen adherence level, and .16 for adolescents with low regimen adherence level. Therefore, the correlation between PA and glycemic control depends highly on the level of regimen adherence or arguably, adherence acts as a buffer in the correlation between PA and glycemic control.

Discussion

The cross-sectional study assessed the associations between PA, HRQoL, regimen adherence, and glycemic control in adolescents with T1D in Jordan. Also, the mean differences between male and female adolescents in reported HRQoL, PA, regimen adherence and HbA1C were examined. Finally, the prediction of the HbA1c level by PA, HRQoL and regimen adherence levels and the interactions between the variables was explored.

Overall, only 14.8% of the participants in the current study demonstrated normal glycemic control (HbA1c $\leq$7.5%). This is in line with the data that few of the adolescents with T1D achieve the recommended target (Livingstone et al., 2012; Mohammad, Farghaly, Metwalley, Monazea, & Abd El-Hafeez, 2012). Further, our results indicated that age was not associated with glycemic control. This contradicts the results supported by several studies indicating that glycemic control decreases with advancement in age (Vanelli et al., 2005; Aljabri & Bokharim 2013; Clements et al., 2014). Several explanations might be that the current sample was small, considering limited age range (12-18), and the majority of the participants (79.9%) were aged between 12 and 15 years.

It is noticeable to report that disease duration was a significant predictor of glycemic control. Adolescents with longer disease duration since age of onset exhibited higher levels of HbA1c compared with adolescents with shorter disease duration which is supported by other research findings (Mohammad et al., 2012; Esdonk et al., 2017). From a physiological point of view, this could be explained due to the progressive dysfunction of pancreatic beta cells leading to increase insulin resistance and uncontrolled blood glucose. However, longer disease duration may support decreased satisfaction, socio-emotional disadvantage, poor illness perception, which all together may interrupt the adherence and subsequently, glycemic control.

The primary finding was as hypothesized that the amount of PA measured by MET-minutes per week inversely correlates with HbA1c level, suggesting that by increasing the amount of performed PA, a moderate decrease in HbA1c percentage is expected. This finding was also supported by the results in the regression analyses where improvement in HbA1c was predicted by level of PA as measured by MET-minutes per week. This is consistent with previous studies on the effect of PA on glycemic control in pediatric population with T1D (Gusso, Pinto, Baldi, Robinson, Cutfield, & Hofman, 2012; Miculis, De Campos & da Silva Boguszweski, 2015; Nguyen et al., 2015; Carabott Pawley, Damato, Torpiano, & Caro, 2016) and with what was suggested by two recent meta-analyses that physically active adolescents with T1D demonstrated improved glycemic control (Tonoli et al., 2012; Quirk et al., 2014). Despite that, several studies did not support the beneficial effects of PA on glycemic control (Aman et al., 2009; Galler et al., 2011; Kennedy et al., 2013). These differences might be explained by several reasons including varied research designs, small sample size, and type, duration, and frequency of

PA investigated across the studies. Therefore, it is suggested that the benefits are mostly dependent on the type, intensity, duration, and frequency of the activity.

In the Arab world, there are few studies investigated the effect of PA on glycemic control in adolescents with T1D. A recent study conducted in Saudi Arabia in 2015 aimed to correlate PA with glycemic control in children with T1D. The study findings were in line with our findings where lower HbA1c levels were found in patients with more frequent PA (Al-Agha, Alrefaie, Elhameed, Ahmad, & El-Derwi, 2015). However, participants in the current study were within the acceptable range of PA, about one-third of them only reported performing vigorous PA, and regular habitual PA of light to moderate intensity appeared to be the dominant form and induced the observed positive effect on glycemic control. This might be explained by several reasons. Where fear of hypoglycemia during and after exercise is suggested to be the likely main barrier to PA in children and adolescents with T1D (McGill & Levitsky, 2016; Roberts, & Taplin, 2015), the cultural components and family structure in Arab countries may also contribute to the situation. This statement is strongly supported by a recent large cross-cultural study conducted to explore the personal, social, and environmental barriers to PA among adolescents in seven Arab countries (Jordan, Syria, United Arab Emirates, Palestine, Libya, Kuwait, Algeria) (Musaiger et al., 2013). The main barriers to PA in the study were low social support, lack of motivation to do PA, and lack of time to participate in PA. These barriers were faced more by females than males within each country and across all countries (Musaiger et al., 2013). Although fear of severe hypoglycemia is a strong and evident factor to consider, strategies to overcome barriers to PA among Arab adolescents need to take into consideration the social support from parents, teacher, and

peers, socio-cultural factors, motivational factors, and accessibility of PA facilities in and out schools. In respect to the study findings, there is lack of PA type-specific analysis due to the used scoring criteria, and PA was measured by the level of energy expenditure which is multi-factorial and could not be determined by use of a self-report questionnaire.

Patient adherence is important for effective outcomes of any medical treatment. Failure to adhere with diabetes treatment regimens can worsen glycemic control that can lead to negative clinical outcomes (Borus & Laffel, 2010). In the current study, there was an inverse correlation between regimen adherence and glycemic control, suggesting that by increasing level of regimen adherence, a moderate decrease in HbA1c percentage is expected. This finding also appeared in the regression analysis where improvement in HbA1c was predicted by level of regimen adherence. This is in line with the literature where several studies suggested that regimen adherence is a core component in improving glycemic control in adolescents with T1D independent of age and disease duration (Ellis, Naar-King, Chen, Moltz, Cunningham, & Idalski-Carcone, 2012; Nansel, Iannotti & Liu, 2012; Holmes, Chen, Mackey, Grey & Streisand, 2014). Moreover, the meta-analysis by Hood and colleagues (2009), confirmed that as regimen adherence increases, HbA1c decreases with a mean effect size of -.32 at 95%*CI* across 21 studies (Hood et al., 2009).

Further, the combination of regimen adherence and PA was found to be predictive of better glycemic control independent of age and disease duration effects. This reflects the ADA (2017) and Healthy People 2020 recommendations for improving glycemic control through a combination of daily PA and adherence to treatment components (Office of Disease Prevention and Health Promotion, 2016, ADA, 2017). It is also highly

debatable that deterioration in glycemic control in adolescents with T1D is strongly related to the hormonal and physiological changes occurred at puberty (Chowdhury, 2015). However, being physically active and more adherent to the recommended regimens may positively advocate for better glycemic control in the context of our study.

Health-related quality of life has increasingly been considered as an essential component of chronic disease treatment. Also, more emphasis has been given to assessing, monitoring, and studying the HRQoL of adolescents with T1D (Abdul-Rasoul et al., 2013). The current study found that HRQoL was below average in the entire sample which is consistent with what is reported by Al-Akour et al. (2010) in a sample of 145 Jordanian adolescents with T1D when HRQoL was significantly reported as low (Al-Akour et al., 2010). Moreover, this is supported by several previous studies (Kalyva, Malakonaki, Eiser & Mamoulakis, 2011; Al-Hayek et al., 2014; Murillo et al., 2017). This might be explained by that the presence of T1D at this age increases the demand for the adolescents and their families to manage the disease and maintain glycemic control. In addition to that, and taking into consideration that the sample was primarily females, the nature of culture may play a major role in shaping this low level of HRQoL where adolescents especially females have limited accessibility to treatment components.

Further, the Pearson's correlation analysis supported by the regression analyses showed no association between reported HRQoL and glycemic control, which is consistent with some previous studies (Bas et al., 2011; Caferoğlu, İnanç, Hatipoğlu & Kurtoğlu, 2016). On the other hand, several studies reported an inverse association between HRQoL and HbA1c (Tahirović, Toromanović, Tahirović, Begić & Varni, 2012; Samardzic, Tahirovic, Popovic & Popovic-Samardzic, 2016; Hassan, Musa, Hai, Fathy &

Ibrahim, 2017). Some potential reasons that might explain our results include the low sample size with lack of a healthy control comparison. Moreover, inconsistency was identified in measuring instruments used in the mentioned studies, where some studies assessed HRQoL using the generic HRQoL scale, while this study used a diabetes-specific HRQoL scale. Further, the scale asks respondents to report their HRQoL for the preceding month which could be considered as a source of recall bias.

Strengths and Limitations

Despite the findings, this study has various strengths and limitations. The main strength of the current study is the fact that that it is the first study conducted in Jordan to assess PA and regimen adherence with relation to glycemic control in adolescents with T1D. Moreover, it gives foundational data on the levels of PA and regimen adherence and their associations with glycemic control. Further, the bivariate and multivariate analyses were conducted using the averaged HbA1c of the recently available values, which decreases the variability between subjects and ensures greater stability of the results.

In contrast, several limitations were noted. The utilization of cross-sectional design limits the ability to draw causal-effect relationship. However, there were significant associations between PA, regimen adherence and glycemic control, temporality remains unclear whether being physically active promotes glycemic control or having good glycemic control motivates adolescents to engage in daily physical activities. Furthermore, the sample size was small and recruitment was done using a non-probability convenience sampling technique yielding a non-representative sample of the

study population. Therefore, the generalizability of the findings is limited and future research is needed on larger samples using random selection techniques.

Additional consideration is that the data were largely based on self-report. Although the study used valid and reliable culturally-adapted instruments, self-report instruments are inherently susceptible to information bias and recall bias with a chance of overestimation of the studied variables. Moreover, the proposed study was to include participants with at least three HbA1c values, several participants had done their glycemic measurements outside the study setting, and the researchers did not have access to outside medical records. Finally, conducting several statistical analyses may increase type 1 error; however, our results were somehow consistent entirely and in line with the empirical findings from previous studies on adolescents with T1D.

Conclusion and Recommendations

Based on the study findings, only 14.8% of the participants demonstrated normal glycemic control (HbA1c ≤7.5%). There were no significant gender differences in glycemic control, PA, HRQoL, and regimen adherence. Jordanian adolescents with T1D aged between 12 and 18 years old were within the acceptable range of PA (1946.3 ± 1321.91) MET-minutes per week, found to demonstrate below-average HRQoL (47.70 ± 10.32), and with moderate regimen adherence levels (38.09.36 ± 8.86). It was found that glycemic control measured by HbA1c was significantly positively correlated with disease duration and inversely with PA and regimen adherence. Participants with poor control had a statistically significant lower mean PA of MET-minutes/week, lowered regimen adherence levels, and longer disease duration compared with better glycemic control. There was no significant association between glycemic control and HRQoL. The findings

also showed that PA, regimen adherence, and disease duration are significant predictors of glycemic control independent of age and HRQoL. However, the combination of increase in levels of PA and regimen adherence would yield a significant reduction of HbA1C independent of disease duration, HRQoL, and age.

Although there were some limitations, the study provides valuable data for glycemic control, PA, HRQoL, and regimen adherence among adolescents with T1D in Jordan. Also, the results highlight the importance of PA, HRQoL, and adherence in the management of T1D in adolescents. Caregivers at different levels (home, hospitals, and schools) are advised to consider the importance of factors associated with the glycemic control that would help with the integration of more effective measures to prevent diabetes-associated complications. Finally, further research is needed to build on this study and provide more information on psychosocial and cultural factors that impact glycemic control and subsequently the quality of life in this population.

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Table 1

Demographic Characteristics of the Study Population (N=74)

Characteristic	*Frequency*	*Percentage*
Gender		
Male	29	39%
Female	45	61%
Living with Both Parents		
Yes	70	94.6%
No	4	5.4%
Parent Marital Status		
Yes	71	95.9%
No	3	4.1%
Father Education		
Less Than High School	14	18.9%
High School	32	43.2%
College Degree	13	17.6%
Bachelor Degree	14	18.9%
Master Degree	0	0%
Doctoral Degree	1	1.4%
Mother Education		
Less Than High School	14	18.9%
High School	28	37.8%
College Degree	22	29.7%
Bachelor Degree	10	13.5%
Master Degree	0	0%
Doctoral Degree	0	0%
Father Employment		
Unemployed	5	6.8%
Part-time	18	24.3%
Full-time	51	68.9%
Mother Employment		
Unemployed	60	81.1%
Part-time	6	8.1%
Full-time	8	10.8%
Age (M± SD)	14.15 ± 1.55	

Note. M = mean; SD = standard deviation.

Table 2

Clinical Characteristics of the Study Population (N=74)

Variable	*Mean(SD)*	*Median*	*Range*	95% CI	
				LL	*UL*
Disease Duration (Year)	5.15 (2.44)	5	9	4.58	5.71
Age at Diagnosis (Year)	8.99 (1.97)	9	10	8.54	9.45
BMI (kg/m^2)	22.0(4.47)	21.5	23.8	20.96	23.04
Daily Insulin Injections	2.76 (.65)	3	3	2.60	2.91
Daily Glucose Measurements	2.51 (.78)	3	5	2.33	2.69
Diabetes Hospitalizations	1.38 (1.10)	1	4	1.12	1.63
Episodes of Hypoglycemia	2.47 (1.68)	2.5	6	2.08	2.86

Note. BMI = body mass index; SD = standard deviation; CI = confidence interval; LL = lower limit; UP = upper limit.

Table 3

Descriptive Statistics of HbA1C, PA, HRQoL, and Regimen Adherence (N=74)

			HRQoL Dimensions						PA (MET-min/week)				Adherence
Gender		HbA1C	I	II	III	IV	V	Total	V	M	W	Total	Total
Male	*Mean*	10.47	33.38	58.97	57.39	20.68	63.96	44.83	2496	831.07	937.24	1946.30	39.44
	SD	2.68	18.20	9.61	10.13	26.22	24.98	9.52	3238	710.68	697.58	1321.91	7.84
	n	29	29	29	29	29	29	29	10	28	29	27	29
Female	*Mean*	9.80	41.50	60.00	59.80	28.81	65.55	49.55	1115	684.49	954.36	1848.82	37.22
	SD	2.89	21.24	12.59	12.74	24.42	22.09	10.50	1492	589.63	880.36	1760.82	9.16
	n	45	45	45	45	45	45	45	13	39	44	45	45
Total	*Mean*	10.06	38.31	59.60	58.86	25.62	64.92	47.70	1715	745.75	947.56	1885.38	38.09
	SD	2.81	20.37	11.46	11.77	25.28	23.11	10.32	2448	641.95	807.57	1601.13	8.68
	n	74	74	74	74	74	74	74	23	67	73	72	74

Note. HbA1C = glycated hemoglobin; HRQoL = health-related quality of life; PA = physical activity; MET = metabolic equivalents; HRQoL dimension I= diabetes symptoms; dimension II= treatment problems; dimension III = treatment adherence; dimension IV = worry; dimension V = communication; PA-V= vigorous physical activity; M-PA = moderate physical activity; W-PA = walking physical activity; SD = standard deviation.

Table 4

Independent Samples Student's t-tests (N=62)

								95% CI	
Variable	Gender	*n*	*Mean*	*SD*	Δ Mean	*t*	*p*	*LL*	*UL*
Averaged HbA1C (%)	Male	23	9.9	2.47	.163	2.38	.813	-1.20	1.53
	Female	39	9.7	2.67					
HRQoL	Male	23	46.5	9.48	-3.23	-1.2	.227	-8.53	2.07
	Female	39	49.7	10.42					
PA (MET-min/week)	Male	21	2110.6	1401.3	223.53	.479	.633	-708.97	1156.05
	Female	39	1887.12	1867.6					
Regimen Adherence	Male	23	38.47	8.34	1.78	.762	.449	-2.90	6.47
	Female	39	36.69	9.22					

*Note.*HbA1C = glycated hemoglobin; HRQoL = health-related quality of life; PA = physical activity; MET = metabolic equivalents; n = number of subjects; SD = standard deviation; Δ Mean = mean difference; t = t statistics; p = significance value; CI = confidence interval; LL = lower limit; UP = upper limit

Table 5

Pearson's Correlations between Glycemic Control and Measured Variables (N=62)

	HbA1C	
Variable	*r*	*p*
Age	.12	.354
Disease Duration	.24	.060
BMI	-.013	.923
Daily Insulin Injections	.044	.733
Daily Glucose Measurements	-.216	.091
Episodes of Hypoglycemia	-.371	.003**
HRQoL	.073	.570
PA(MET-min/week)	-.328	.010*
Regimen Adherence	-.299	.018*
Sedentary PA	.337	.009**

*Note.*HbA1C = glycated hemoglobin; BMI = body mass index; HRQoL = health-related quality of life; PA = physical activity; MET = metabolic equivalents; r = Pearson's correlation; p = significance value.
*$p < .05$. **$p < .01$.

Table 6

Spearman's rank-order Correlations between Glycemic Control and Categorical Variables (N=62)

	HbA1C	
Variable	r_s	*p*
Participant's Education	.064	.622
Father Education	-.159	.216
Mother Education	-.097	.454
Father Employment	-.091	.480
Mother Employment	.005	.967

*Note.*HbA1C = glycated hemoglobin; r_s = spearman's correlations; p = significance value
Correlation is significant at the 0.05 level (2-tailed).

Table 7

Unadjusted, Adjusted, and Interaction Regression Models Predicting Glycemic Control

Predictor	Unstandardized *B*	*SE B*	*p*	VIF	Δ R^2	Δ*F*	*p* (Δ*F*)
Model 1 (Unadjusted)					.228	5.52	.002**
HRQoL	-.163	.140	.249				
PA	-.367	.120	.003**				
Regiment Adherence	-.409	.140	.005**				
Model 2 (Adjusted)					.322	3.72	.031*
Age	-.266	.156	.093	1.83			
Disease Duration	.444	.163	.009	1.97			
HRQoL	-.023	.143	.871	1.60			
PA	-.360	.117	.003**	1.05			
Regimen Adherence	-.475	.136	.001**	1.43			
Model 3 (Interaction)					.434	3.35	.026*
Age	-.317	.161	.055	2.22			
Disease Duration	.411	.158	.012*	2.10			
HRQoL	.003	.149	.984	1.28			
PA	-.488	.121	.000***	1.98			
Regimen Adherence	-.373	.135	.008**	1.61			
PA × HRQoL	.025	.173	.885	1.73			
PA × Adherence	-.304	.133	.027*	1.80			
HRQoL × Adherence	-.266	.157	.096	1.39			

Note. Dependent variable is glycemic control measured by glycated hemoglobin (HbA1C).
SE B = standard error of beta; VIF= variance inflation factor; HRQoL = health-related quality of life; PA = physical.
Model 1 includes only the main-effects on the three predictors (HRQoL, PA, Regimen adherence).
Model 2 includes the main-effects on the three predictors (HRQoL, PA, Regimen adherence) adjusted for age and disease duration.
Model 3 includes the main-effects on the three predictors adjusted for age and disease duration, and the interaction terms between PA and HRQoL, PA and regimen adherence, and HRQoL and regimen adherence.
All regression models were conducted on the standardized scores.
*p < .05. **p< .01. ***p< .001.

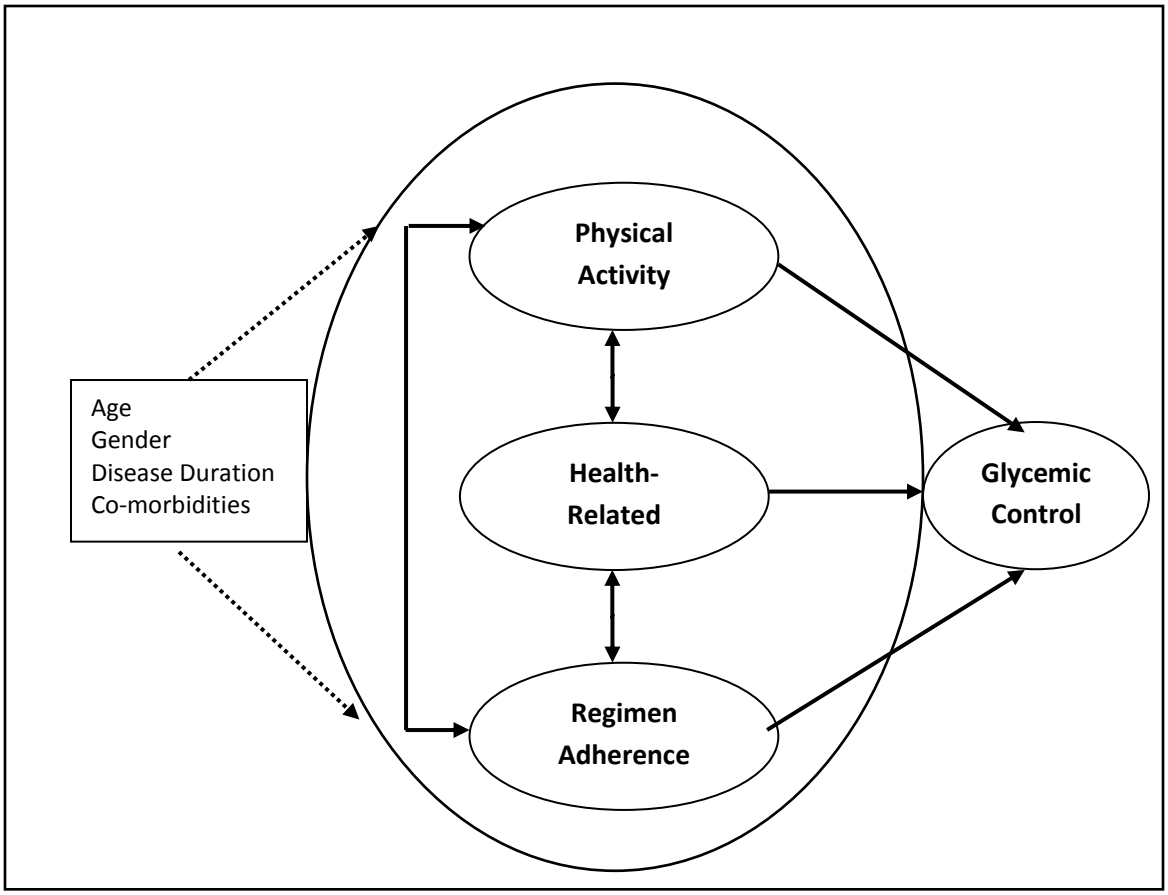

Figure 1. A conceptual framework for glycemic control in adolescents with T1D.

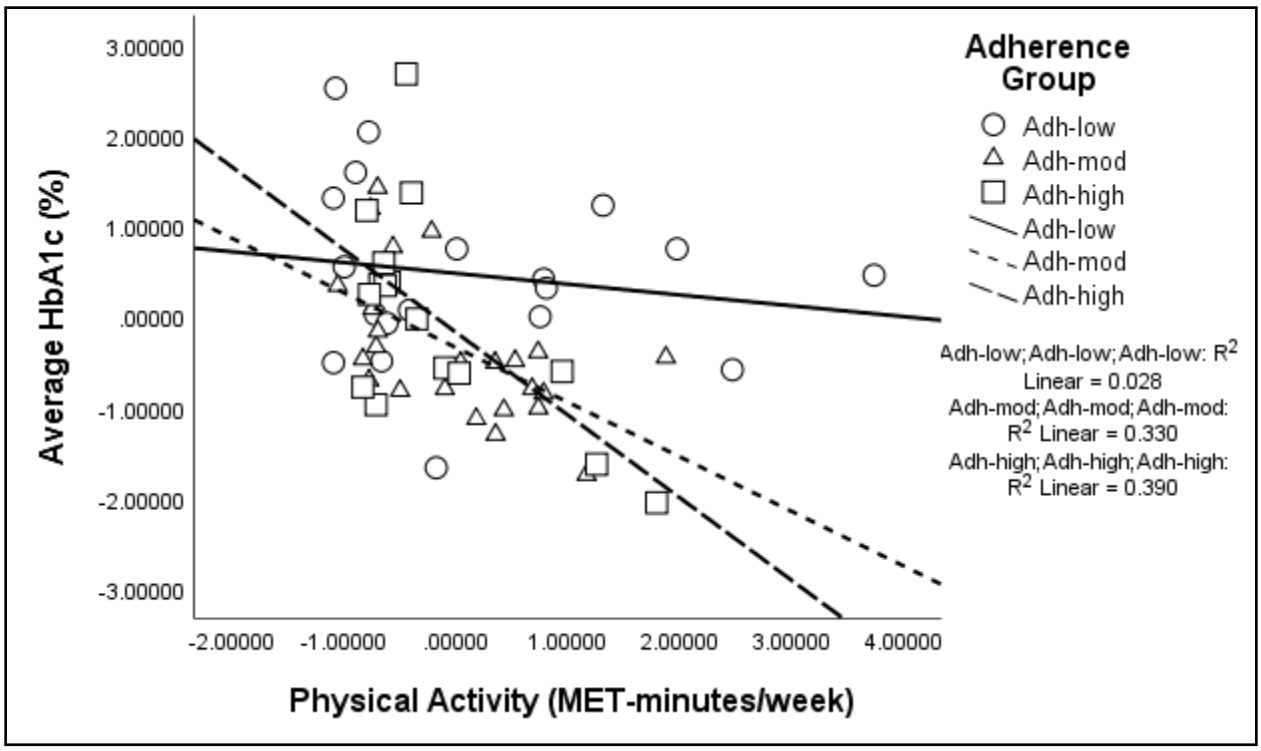

Figure 2. Scatterplot of the interaction between physical activity and regimen adherence in predicting glycemic control. The bold line represents the association between physical activity and glycemic control in participants with low adherence levels. The light-dotted line represents the association between physical activity and glycemic control in participants with moderate adherence levels. The dark-dotted line represents the association between physical activity and glycemic control in participants with high adherence levels.

Submitted Manuscript for Publication

Arabic Translation and Psychometric Evaluation of the Adherence in Diabetes Questionnaire in Jordanian Adolescents with Type 1 Diabetes: Proposal and Protocol

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Abstract

Background: Type 1 diabetes is an autoimmune disease affecting children and adolescents and considered as the second most common chronic condition in this population. Generally, patients with diabetes are advised to adhere to several self-management behaviors to prevent short and long-term associated complications. Accurate assessment of patient adherence is important for effective outcomes of medical treatment. As in case of diabetes, the availability of accurate information on self-care activities level alongside with measures of glycemic control allow health care providers to monitor patients' behavior and adjust their plans and recommendations to enhance diabetes control The aim of this study is to translate the ADQ-C-C version of the ADQ into Arabic and examine the psychometric properties of the Arabic version in Jordanian adolescents with T1D. **Methods**: The psychometric protocol presented in this paper is divided into two phases: (a) Arabic translation of the ADQ-C-C; (b) psychometric testing of the translated version in Jordanian adolescents aged 12 to18 years with T1D. The translation will be guided by the guidelines of translation and cross-cultural adaptation of self-report measures recommended by Beaton, Bombardier, Guillemin, and Ferraz (2000). A cross-sectional study design will be employed to psychometrically assess the ADQ-C-C-Arabic a sample of 500 Jordanian adolescents aged 12 to18 years with T1D. The study will test the final adopted versions for internal consistency reliability using Cronbach's alpha measure, test-retest reliability using The Pearson product moment correlation coefficient, and construct validity using both confirmatory and exploratory factor analyses. The Item Response Theory of measurement will be utilized to evaluate the psychometric performance of the Arabic version of the ADQ-C-C using the Graded

Response Model of fitness. **Discussion:** Since there has been little research on diabetes self-care activities in Jordanian adolescents with T1D and the search of literature showed no available Arabic version instrument that has been used to measure regimen adherence, the outcome of this study will produce a valid and reliable Arabic version of the source questionnaire (ADQ) that could be used to measure regimen adherence in Arabic speaking adolescents with T1D.

Keywords: psychometrics, validity, reliability, item response theory, type 1 diabetes, adolescents, adherence, cultural-adaptation.

Background

Type 1 diabetes is an autoimmune disease affecting children and adolescents and considered as the second most common chronic condition in this population. [1] Type 1 diabetes is a serious condition associated with significant morbidity and mortality due to both acute and long-term complications. [2] Generally, patients with diabetes are advised to adhere to several self-management behaviors to prevent short and long-term complications. Disease management is more challenging for patients with T1D as they are required to follow a lifelong therapy. [3] The recommended regimen for T1D includes frequent checking of blood glucose levels, daily administration of insulin injections or use of an insulin pump, regulating carbohydrate intake, and performing daily physical exercises. [4] Accurate assessment of patient adherence is important for effective outcomes of treatment. As in case of diabetes, the availability of accurate information on self-care activities level with measures of glycemic control allow health care providers to monitor patients' behavior and adjust recommendations that enhance diabetes control. [5] However, there has been little research on diabetes self-care activities in Jordanian adolescents with T1D and the search of the literature showed no available Arabic version instrument that has been used to measure self-care adherence. Therefore, the aim of this study is to translate the Adherence in Diabetes Questionnaire (ADQ) [6] into Arabic and psychometrically test it in Jordanian adolescents aged 12 to18 years with T1D**.**

Adherence is a concept widely used to reflect one's ability to follow healthcare advice and achieve effective clinical outcomes. The term adherence originated from behavioral sciences and was adopted to be used instead of compliance. [7] The World Health Organization defined adherence as "the extent to which a person's behavior

(taking medications, following a recommended diet, and/or executing lifestyle changes) corresponds with the agreed recommendations of health professionals". [8] The definition also includes the "active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result". [9] Adherence to diabetes treatment is typically measured by the number of times the patient administers insulin at the prescribed times, self-monitors blood glucose follows the prescribed diet, and performs physical exercises at least 20 minutes a day. [10] There is no standard method for measuring adherence, and all measurement approaches include both direct and indirect measures. Direct measures of adherence behavior include the assessment of metabolite blood levels and the measurement of clinical outcomes of diabetes such as glycated hemoglobin. However, these methods are expensive, depend on information technology, require training, and provide a general reflection of adherence to the therapeutic regimen (i.e. elevated glycated hemoglobin could indicate low adherence to insulin regimen and/or diet). [11]

Indirect measures of adherence behavior include self-report questionnaires, parents' reports, healthcare provider reports, and structured interviews. These methods are less expensive, easy to administer, and provide more details on patient's adherence to specific management tasks. However, these methods are prone to several types of information bias such as recall bias, interviewer bias, and prevarication bias. [12] On the other hand, self-report questionnaires demonstrated effective evaluation of adherence. [12] However, when patients rate their degree to which they follow the recommended therapeutic regimen they overestimate adherence due to several factors such as wording and the structure of the questions. [13]

As adolescents receive complex and intensive medical regimens, it becomes critical to have psychometrically robust assessment methodology to monitor their adherence. [14] For the purpose of this study, adherence is conceptually defined as the extent to which an individual's action or behavior coincides with advice or instruction. Several self-report measures have been developed to measure adherence such as Diabetes Self-Management Profile–Self Report (DSMP-SR) [15], Diabetes Management Questionnaire (DMQ) [16], and ADQ. [6]

The DSMP-SR [15] is a 24-item self-report or parent-report questionnaire developed to measure adherence in children and adolescents with T1D aged ≥ 11years old. The instrument was developed based on the DSMP interview guide [17] to decrease the requirement for trained interviewers to conduct the DSMP interviews. The instrument has separate versions for patients on insulin pump versus conventional daily insulin injections. [15] Items inquire about how often adolescents adhere to specific diabetes management task and respondents select answers from 3 to 6 options for each question. Psychometric properties of the DSMP-SR were evaluated in a sample of 151 youth with T1D. [15] Evidence of reliability includes Cronbach's alpha of .82 for youth and .80 for parents suggesting adequate internal consistency. [18] With no available data to support the construct validity of the instrument, results on convergent validity showed moderate correlations between DSMP-SR and PedsQL diabetes module for youth and parents (r = .37 and .49, respectively). [15]

The DMQ [16] is a 20-item instrument developed to measure adherence to diabetes self-management tasks in children with T1D over the last month of therapy. [16] The instrument has five subscales as follows: physical activity (3 items), meal and snack

time (8 items), low blood sugar (3 items), high blood sugar (3 items), and insulin and blood sugar monitoring (3 items). Response options are based on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). The content of the DMQ was based on previously developed instruments including the self-care inventory and the diabetes self-management profile. [16] Psychometric properties of the DMQ were evaluated in a sample of T1D children (N =273). Evidence of reliability includes Cronbach's alpha (α) of.79 [16], suggesting inadequate internal consistency, and test-retest coefficient of .65 with a 6-week interval [16]; suggesting inadequate stability of the instrument. [18] Results on convergent validity indicated a moderate correlation between the DMQ scores and blood glucose monitoring frequency (r = .36). [16]

The Instrument

The ADQ [6] is a 17-19-item self-report questionnaire developed to evaluate adherence behavior activities of adolescents and children with T1D. [6] The instrument has two versions based on insulin modality; ADQ-I has 17 items pertaining to adherence for patients on insulin pump, whereas ADQ-C has the same 17 items in the ADQ-I with two additional items related to adherence for patients on conventional insulin administration. The aim is to assess adolescents' adherence to daily diabetes treatment practices including physical activity, dietary management, insulin administration and adjustment, collaboration with caregivers, and daily glucose measurement. Both ADQ-I and ADQ-C have a separate self-report version for children aged 10 years and older; ADQ-I-C and ADQ-C-C, plus a separate version for parents or caregiver of children younger than 10 years; ADQ-I-P and ADQ-C-P with similar item content. [6] Respondents rate each item on a 5-point Likert scale ranging from 1 = "have not done it

at all" to 5 = "have always done it". The measurement framework for this instrument is norm-referenced measurement where higher mean scores indicate greater adherence. [6] The development of the ADQ was based on a previously developed instrument that measures adherence in patients with diabetes; the Diabetes Behavior Rating Scale (DBRS). The instrument was found to be easy to read and takes less than 10 minutes to complete. [6]

Psychometric properties of the ADQ were evaluated in a sample of 1028 caregivers and 766 adolescents (aged 10-17) with T1D. [6] All versions of the ADQ demonstrated satisfactory internal consistency with $\alpha = .85$ for the ADQ-C-C; .82 for the ADQ-I-C; .89 for the ADQ-C-P; and .86 for the ADQ-I-P. [6] Construct validity showed a four-factor solution for ADQ-C-P and ADQ-I-P with almost all items uniquely loaded ($\geq .40$) onto each factor suggested in the final solution of the ADQ. [6] Convergent validity results showed a significantly strong correlation between the ADQ items and a parallel measuring scale (The Self-Efficacy for Diabetes Self- Management) items ($r = .61$, $p= .001$). [6] Thus, this instrument meets the a priori criteria for reliability ($\geq .80$), convergent validity ($\geq .50$), factorial validity, and readability. The ADQ is simple, easy to complete, has separate versions for patients on insulin pump and patients on conventional daily insulin injections, has acceptable psychometric properties, and adequately covers adherence activities with regard to insulin administration, physical activity, monitoring blood glucose, diet, management of hypo and hyperglycemia, appointment keeping(repeat of above). Furthermore, the instrument asks adolescents to report what they actually do regarding the diabetes treatment plan in the preceding month, which decrease the risk of recall bias compared with 2-3 months in other

instruments. In addition, the instrument is available in the public domain and can be used for free. For the proposed study, adherence is operationally defined by measuring self-reported self-care behaviors in the preceding month as score in the Arabic version of the ADQ. While the population in this study will be adolescents aged between 12 and 18 years, the translation will be performed for ADQ-I-C and ADQ-C-C. Since the first 17 items are similar in both versions, and ADQ-C-C has two additional items for patients on daily insulin injections, the study will translate and psychometrically test the ADQ-C-C, and from the final adopted version, a separate version will be created for patients on insulin pump by removing the last two items.

Methods and Design

The aim of this study is to translate the ADQ-C-C version of the ADQ into Arabic and examine the psychometric properties of the Arabic version in Jordanian adolescents with T1D. It is anticipated that the translation process and data collection will commence in November 2017 and continues through April 2018.The psychometric protocol presented in this paper is divided into two phases. The successful completion of the first phase will produce an Arabic version of the questionnaire (ADQ-C-C-Arabic) with initially accepted psychometric properties that will be further tested for reliability and validity in a larger sample of Arabic speaking adolescents with T1D. The second phase includes the psychometric evaluation of the adapted version in a larger sample (N=500) of Jordanian adolescents aged 12 to 18 years with T1D. The outcome of this phase is to produce a valid and reliable Arabic version of the source questionnaire (ADQ) that could be used to measure regimen adherence in Arabic speaking adolescents with T1D.

Phase I: Translation and Cross-Cultural Adaptation of the ADQ-C-C

The translation will be guided by the guidelines of translation and cross-cultural adaptation of self-report measures recommended by Beaton et al [19]. The guidelines include five consecutive stages as follows: initial translation, synthesis of the translations, back translation, expert committee, and test of the pre-final version. First, the PI will send an e-mail letter to the original developers of the ADQ requesting for permission to proceed with the translation and use of the instrument for research purposes. After receiving the permission, the guidelines of translations will be followed.

Phase 1.1: Initial Translation

Two forward translations of ADQ-C-C will be made from English to Arabic by two independent bilingual translators whose native language is Arabic. One of them will be a certified endocrinologist who is aware of the study's purpose and goals, and the other one will be a linguistics faculty who has no clinical or medical background and will be blinded to the concepts being quantified in the questionnaire. Both translators will be simultaneously be given the same instructions for translation. Each translator will produce a translated version of the instrument combined with a written report of the translation. The PI will assign each translated version with the initial name as follows: ADQ-C-C-T1 and ADQ-C-C-T2.

Phase 1.2: Synthesis of the Translations

Both translators will be advised to schedule a meeting to discuss the differences between their translations, highlight challenging phrases or uncertainties, and resolve any differences. Both translations (ADQ-C-C-T1 and ADQ-C-C-T2) with the original

questionnaire (ADQ-C-C) will be synthesized to produce a common translated version that will be called ADQ-C-C-T3. This phase will be concluded with a written report documenting the synthesis process, addressed issues, and how they resolved each issue.

Phase 1.3: Back Translation

Two back translations of the ADQ-C-C-T3 version into English will be done by two independent bilingual translators whose native language is English. The two translators have no clinical or medical background and will not be aware of the concepts being explored. The back translations will be conducted with no prior exposure to the English version of the questionnaire. Two independent versions will be produced in this stage: back translation 1 (ADQ-C-C-BT1), and back translation 2 (ADQ-C-C-BT2). The purpose behind this process is to confirm that the back-translated versions are contently identical to the original version. A synthesis of these translations will be performed to produce one common translation and the PI will give a name for this version as ADQ-C-C-BT3.

Phase 1.4: Expert Committee

Phase 1.4.1: An expert committee will be formulated to discuss any discrepancies between the original ADQ-C-C items and the back-translated version of the instrument. The committee will consist of two endocrinologists, one pediatrician, two diabetes nurses, an Arabic language expert, the translators (forward and back-translators), and the PI. The diversity of the expert committee is to consolidate the process and enrich the content validity of the questionnaire. The end result of this sub-phase is to integrate all translated version of the questionnaire and create a unified version that would be considered as the pre-final version for field testing. The decision on the equivalency

between the original and the developed versions will consider the concepts of idiomatic, semantic, experiential, and conceptual equivalencies.

Phase 1.4.2: Once the agreed version is obtained (ADQ-C-C-Arabic-1), content validity will be examined using the content validity index (CVI). The aim of this analysis is to examine the appropriateness of the ADQ-C-C-Arabic-1 in measuring adherence in Arabic-speaking adolescents with T1D. To conduct the content validity analysis, the PI will invite a larger number of experts from the field of diabetes management.

The content validity of the adopted version of the ADQ-C-C will be tested with a committee of experts in diabetes care using the CVI. The CVI will be computed for each item (I-CVI) and for the total scale (S-CVI). The I-CVI represents the percentage of experts who consider an item clearly represents the content, while S-CVI represents the percentage of items considered as clearly represent the content by all experts. [20]The PI will develop a content validity questionnaire in which each item in the ADQ-C-C-Arabic1 version is rated on a 4-point Likert scale: 1) not clearly represent the content; 2) somewhat clear and represent the content; 3) quite clear and represent the content; 4) highly clear.

Content validity questionnaire exemplar:

Item	Clearly represent the content	Comment
Planning meals in accordance with the system that you've been taught?	1 2 3 4	

Note: The questionnaire will be in Arabic

After ranking by the panel members, the PI will dichotomize the ratings of 3 or 4 as clearly represent the content item and ratings of 1 or 2 as not clearly represent the content item. The PI will calculate the I-CVI for each item by dividing the number of experts who rated the item with 3 or 4 (clearly represent the content), by the total number of experts. For example, if an item was rated as clearly represent the content by 8 out of 10 experts, the I-CVI for this particular item will be .80. For this study, the following a priori criteria of the I-CVI are established: ≥ .80 indicates acceptable content validity of individual item; ≤ .60 and ≥ .79 indicates revision, and ≤ .59 indicates deletion or substitution. The averaging calculation method will be used to compute the scale-level content validity index (S-CV1/Ave) by calculating the average of the I-CVIs for all items on the scale. A priori S-CV1/Ave of ≥ .80 is established for acceptable content validity and that the first Arabic version of the scale is semantically equivalent to the ADQ-C-C.

Phase 1.5: Test of the Pre-final version (ADQ-C-C-Arabic-2)

The final product of the translation process will be the Arabic version of the instrument (ADQ-C-C-Arabic-2). A separate version for patients on insulin pump will be created by removing the last two items and will be named as ADQ-I-C-Arabic-2. The final versions will be pilot tested for face validity in a sample of 60 Jordanian adolescents with T1D, 30 adolescents on daily insulin injections modality, and 30 adolescents on insulin pump. The study proposal will be submitted to the Ethics Committee of University of Texas Health Science Center at Houston and King Abdullah University Hospital (KAUH), Jordan, for ethical approval. The selected participants will be asked to complete the ADQ-C-C-Arabic-2 when they are waiting to be seen by the physician or after they finish their appointment. The PI will provide the participant the ADQ-C-C-

Arabic-2and explain how to respond to each item in term of the extent that each item best describes how he/she have managed his/her diabetes care in the preceding month using the following scale: 1 = “Have not done it at all”, 2 = “Have seldom done it”, 3 = “Have done it about half the time”, 4 = “Have usually done it”, and 5 = “Have always done it”. A mini-cognitive interview will be conducted with each participant when they finished the questionnaire to get a deeper understanding of what each item and response meant to the respondent. The PI will ask each participant for any further comments and if they struggled with any item or was difficult to understand. To examine face validity of the ADQ-C-C-Arabic-2, participants will be asked to rate the ability of the scale to measure adherence as it appears to them using the following Likert scale: 1) the scale is extremely suitable, 2) the scale is very suitable, 3) the scale is adequate, 4) the scale is inadequate, and 5) the scale is irrelevant and therefore unsuitable. A priori criterion of 80% of the participants reported each scale as valid is established to assume that the Arabic versions are culturally adapted and ready for further psychometric evaluation. In addition, the following operational specifications will be considered in the adaptation of the translated version: the instrument is semantically equivalent to the ADQ, is self-administered; easy to read; appropriate for adolescents aged 12-18 years; takes between 10 to 15 minutes to complete; and covers adherence to medication, diet, exercise, glucose management, and insulin regimen; evidence of reliability in Arabic speaking adolescents with T1D $\geq$.80 and evidence of validity $\geq$ .50.

Phase II: Further Testing of the Adapted Version

The aim of this phase is to evaluate the consistency of the ADQ-C-C-Arabic and ADQ-I-C-Arabic to accurately measure adherence among Arabic-speaking adolescents with T1D.

Study design and participants. A cross-sectional study design will be employed to psychometrically assess the ADQ-C-C-Arabic and ADQ-I-C-Arabic in a convenience sample of Jordanian adolescents aged 12 to18 years with T1D. The study will test the final adopted versions for internal consistency reliability, test-retest reliability, and construct validity. Inclusion criteria for study participants are as follows: Jordanian adolescents diagnosed with T1D, age between 12 and 18 years, initiated on treatment that includes daily insulin injections or insulin pump, and able to read and write Arabic.

Item Response Theory (IRT) of measurement will be utilized to evaluate the psychometric performance of the Arabic version of the ADQ-C-C. IRT is a system of statistical models that describes one way of determining the consistency between latent traits and their manifestations. IRT is applied to minimize the bias and maximize the measurement power of psychological tests and psychometric questionnaire. [21] In healthcare, several concepts demonstrate the pattern of continuity which may be ranked from lowest to highest such as adherence and quality of life. In this case, scale development should consider the way in which items are constructed and ordered to reflect the underlying latent variable. The IRT allows the researchers to consider the issue of ordering that would provide a better understanding of the concept and measure individual responses more accurately. [22] Since the ADQ-C-C uses the Likert scale in

measuring adherence, the Graded Response Model (GRM), one of the Rasch models used for ordered polytomous data, will be applied in this study. The GRM visualizes the relationship between responses to an item and the trait levels (theta, θ), assuming that an increase in an individual's response will result in a continuum step toward higher degree of the latent variable, here adherence. There are two basic assumptions that must be met when using IRT; unidimensionality and local independence (LI). [21]

Unidimensionality means that the latent variable being measured is, in fact, unidimensional; that is, items in the Arabic version of the ADQ-C-C measure only the underlining construct (i.e. adherence) and the covariance among the items can be explained only by that construct. Confirmatory factor analysis (CFA) and an exploratory factor analysis (EFA) will be conducted to evaluate this assumption. When CFA is applied to test the unidimensionality assumption of the IRT, a model is determined when all items adequately load on a single factor. [23] The CFA for GRM goodness of fit will be assessed based on the following a priori criteria: the Comparative Fit Index of > .95, the Standardized Root-Mean Residual (SRMR) of < .08, the Non-Normed Fit Index (NNFI) of >.95, and the Root-Mean-Square Error of Approximation (RMSEA) of <.06. [24] If the CFA failed to provide best GRM fit, an EFA will be conducted and the unidimensionality of the scale will be accepted if the first extracted factor accounted for 20% or more of the total variance explained by the model or if the ratio of the first 2 eigenvalues exceeds 4. [25] The assumption of LI means that the individual's response to any item does not affect the response for other items. This assumption will be evaluated by examining the residuals extracted from the EFA analysis. The LI will be considered solid criterion for model fit if the residuals approaching zero (≤.20). [25]

The sample size is determined based on the number of subjects needed to achieve an adequate calibration of GRM. According to De Ayala [21], at least 500 subjects will be required. Based on the insulin modality, the ADQ-C-C-Arabic or ADQ-I-C-Arabic will be administered on two separate occasions two weeks apart to calculate test-retest reliability. Authorization will be granted from the personnel in-charge of the selected clinic.

Data Management

Two separate datasets will be created in SPSS for each version; one for the data collected in the first round, and one for data collected in the second round.

Data analysis and interpretation. Statistical analysis will be performed by the Principal Investigator (PI) using SPSS (version 24) and Amos 7.0.

Construct validity. CFA will be used to investigate the construct validity of the ADQ-C-C-Arabic and ADQ-I-C-Arabic. The RMSEA, the CFI, and the SRMR will be computed to evaluate the fitness of the GRM based on the a priori criteria mentioned above. If the CFA failed to prove the goodness of GRM fit, an EFA will be performed using principal axis factoring with orthogonal rotation (Varimax). The Kaiser-Meyer Olkin test $\geq .60$ will be used to determine the sample adequacy for analysis. [26] The number of factors will be determined by Kaiser's rule where only the factors that have eigenvalues greater than one were retained for interpretation. [26] A priori criteria of factor pattern loadings $\geq .40$ with cross-loadings $\geq .20$ [27], and a minimum of three items per factor will be used for acceptable and interpretable factor solution. [28]

Internal consistency reliability. Cronbach's alpha coefficient will be used to evaluate the internal consistency of ADQ-C-C-Arabic and ADQ-I-C-Arabic. Cronbach's alpha coefficient will be computed for the total scale (17 or 19 items). A priori criterion of $\alpha \geq .80$ will be used for adequate evidence of the scales consistency. [18]

Test-retest reliability. The Pearson product moment correlation coefficient (r) test will be used to examine the stability of the instruments. A priori criterion of $r \geq .80$ is established for adequate evidence of stability of the questionnaires. [18]

Discussion

The Arabic language is broadly considered as one of the most difficult languages to use in the translation of instruments, therefore issues in the translation process may arise especially when translating the medical terminology, which might be understood and translated differently by subjects due to the diverse accents that are common in the Arabic language. [29]To account for this issue, the translators will be advised to use popular terms that are age and gender appropriate and can be easily understood by the target population. Moreover, they will be advised to select jargon-free terms and avoid using medical and nursing terms in order to avoid misinterpretation that may arise due to different accents within Jordanian context. [29] Another issue related to the scale use is that the questionnaire is self-report which increase the risk of recall bias. This issue will be minimized by asking the parents to help their children if they cannot exactly remember their self-care activities in the preceding month.

If the instrument demonstrated unsatisfactory psychometric properties in term of reliability and validity, several alternative plans are proposed to be followed. First, if the

pre-final version of the instrument does not meet the a priori criterion for S-CVI, the translation will be replicated. Second, if the instrument failed to demonstrate adequate face validity levels, the PI will conduct small focus groups of Jordanian adolescents with T1D to discuss the contents of the instrument and address any inappropriate contents that may lead to inaccurate measurement of adherence. Third, if the translated instrument is found to have satisfactory levels of content and face validity but failed to meet the a priori criteria for construct validity and/or internal consistency reliability, the translated instrument will be considered invalid and unreliable to measure the concept of interest and the PI will propose a new study protocol to measure regimen adherence using the original ADQ in a sample of English-speaking Jordanian adolescents with T1D. Before data collection, a pilot study will be conducted on a convenience sample of 20 Jordanian adolescents aged 12 to18 years with T1D to test the internal consistency reliability of the ADQ. If the preliminary results showed unsatisfactory levels of the reliability estimates, the PI will search for a new instrument that fits with the operational specifications proposed in this study and replicate the translation and cross-cultural adaptation producer in order to produce a valid and reliable instrument to measure regimen adherence in Arabic speaking population.

List of abbreviations

ADQ: Adherence in Diabetes Questionnaire

ADQ-C: Adherence in Diabetes Questionnaire-Conventional

ADQ-C-C: Adherence in Diabetes Questionnaire-Conventional-Children

ADQ-C-P: Adherence in Diabetes Questionnaire-Conventional-Parents

ADQ-I: Adherence in Diabetes Questionnaire-Insulin

ADQ-I-C: Adherence in Diabetes Questionnaire-Insulin-Children

ADQ-I-P: Adherence in Diabetes Questionnaire-Insulin-Parents

CFA: Confirmatory Factor Analysis

CFI: Comparative Fit Index

CVI: Content Validity Index

DBRS: Diabetes Behavior Rating Scale

DMQ: Diabetes Management Questionnaire

DSMP: Diabetes Self-Management Profile

DSMP-SR: Diabetes Self-Management Profile–Self Report

EFA: Exploratory Factor Analysis

GRM: Graded Response Model

IRT: Item Response Theory

KAUH: King Abdullah University Hospital

LI: local Independence

NNFI: Non-Normed Fit Index

PI: Principal Investigator

RMSEA: Root-Mean-Square Error of Approximation

S-CV1/Ave: Scale-Level Content Validity Index

SRMR: Standardized Root-Mean Residual

T1D: Type 1 diabetes

Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- ***Ethics approval and consent to participate***

The study proposal will be submitted to the Ethics Committee of University of Texas Health Science Center at Houston and King Abdullah University Hospital (KAUH), Jordan, for ethical approvals.

- ***Consent for publication***

Not applicable

- ***Availability of data and material***

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

- ***Competing interests***

The authors declare that they have no competing interests

- ***Funding***

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

- ***Authors' contributions***

YMA is the principal investigator of the study and responsible for the development of the study proposal and protocol and writing the first draft of the manuscript. GLW contributed to the background, methods, and design and will participate in data management, analysis, and interpretation. Both authors have read and approved the final version of the manuscript.

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Appendix A

King Abdullah University Hospital IRB Approval

مستشفى الملك المؤسس عبدالله الجامعي
King Abdullah University Hospital

General Director Office
مكتب المدير العام

ص.ب (٦٣٠٠٠١) اربد (٢٢١١٠) الأردن
فاكس : ٧٠٩٥٧٧٧ (٢-٩٦٢)
هاتف : ٧٢٠٠٦٠٠ (٢-٩٦٢)

Ref. 13/3/2573 الرقم : .....

Date : 30-7-2017 التاريخ : ..... هـ

الموافق : ..... م

Prof. Geri LoBiondo- Wood PhD

Coordinator PhD Nursing Program
University of Texas
Health Science Center
E-mail: Geri.1.wood@uth.tmc.edu

Dear Professor,

In reference to the scientific research which is presented by **Mr. Yousef Aljawarneh**, who is a PhD student at the University of Texas Health Center School of Nursing, entitled:

Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes

We would like to inform you that the IRB Committee has granted Mr. Yousef Aljawarneh the approval to conduct his proposal in the Jordanian Community for the purpose mentioned above, in coordination with Nursing Department at KAUH, under the following conditions:

1. Commitment to the Scientific Research Policy at Jordan University of Science and Technology and King Abdullah University Hospital.
2. Maintaining data confidentiality and using it only for scientific purposes.
3. Participants' legally authorized representative consent form is required.
4. This approval will be canceled if the principle investigator doesn't provide IRB with the final executive study report about the results of the research after one year.

Sincerely,

Prof. Ismail Matalkah

CEO KAUH

Appendix B

The University of Texas Health Science Center at Houston IRB Approval

UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

Yousef Aljawarneh

UT-H - SN - Acute and Continuing Care Dept

NOTICE OF APPROVAL TO BEGIN RESEARCH

October 10, 2017

HSC-SN-17-0852 - Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes

Number of Subjects Approved: Target: /Screen: 150

PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: 10/06/2017

APPROVAL DATE:10/10/2017

EXPIRATION DATE: 09/30/2018

CHAIRPERSON: L. Maximilian Buja, MD L. Maximilian Buja

Subject to any provisions noted above, you may now begin this research.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT DETERMINATION:

Signed Informed Consent Required

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent

process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):

Exempt from HIPAA: This study is being conducted outside the United States and therefore, is not bound by HIPAA laws.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent and HIPAA documents if required, in a manner that ensures subject confidentiality.

Appendix C

Study Flyer – English Version

مستشفى الملك المؤسس عبدالله الجامعي
king Abdullah University Hospital

UTHealth
The University of Texas
Health Science Center at Houston

Volunteers with Type 1 Diabetes Needed for Research Study

This study looks at the relationships between physical activity, health-related quality of life, adherence, and glycemic control in adolescents with Type 1 Diabetes. This study will be conducted by Mr. Yousef Aljawarneh under the supervision of clinical and academic professors from King Abdullah University Hospital in Jordan, and The University of Texas Health Science Center at Houston in the USA.

You may be eligible to participate if:

- You have been diagnosed with Type 1 Diabetes for more than 1 year.
- You are 12 to 18 years old.
- In good general health.

Study details:

As a participant in this study, you will be asked to fill anonymous questionnaires related to the study in a single session which is approximately 15 minutes.

Location:

The Pediatric Diabetes Clinic at King Abdullah University Hospital, 3rd floor, Section C.

Interested?

For more information about the study, or to volunteer for this study, please contact:

Yousef Aljawarneh, Mobile: 00962798**097033**

Dr. Mohammad Aljarrah, Mobile: 00962798167489

Clinic Nurse: 0096227200600

The study has been reviewed and approved by the Research Ethics Committees at KAUH (Jordan) and UTHealth (USA)

Appendix D

Study Flyer – Arabic Version

مطلوب متطوعيين للمشاركة في دراسة بحثيّة عن مرض السكري-النوع 1

يهدف هذا البحث إلى دراسة العلاقة بين النشاط البدني، جودة الحياة ، الإمتثال بالخطة العلاجية، ونسبة السكر التراكمي في الدم لدى المراهقين المصابيين بمرض السكري من النوع 1. وسيجري هذه الدراسة طالب الدكتوراة يوسف الجوارنة تحت إشراف أساتذة سريريين وأكاديميين من مستشفى الملك المؤسس عبد الله الجامعي في الأردن، وجامعة تكساس في هيوستن بالولايات المتحدة الأمريكية.

قد تكون مؤهلاً للمشاركة إذا:

- **تم تشخيصك بمرض السكري- النوع 1 لمدة تزيد عن سنة واحدة.**
- **عمرك 12-18 سنة.**
- **تتمتع بصحة جيدة.**

تفاصيل الدراسة:

كمشارك في هذه الدراسة, سيطلب منك ملء إستبيانات تتعلق بالدراسة في جلسة واحدة و هي حوالي 15 دقيقة.

المكان:

عيادة سكري الأطفال في مستشفى الملك المؤسس عبدالله الجامعي, الطابق الثالث.

مهتم أو ترغب بالمشاركة؟

لمزيد من المعلومات أو المشاركة في الدراسة الرجاء الإتصال بالأرقام التالية:

يوسف الجوارنة , تلفون: 00962798097033

الدكتور محمد الجراح, تلفون: 00962798167489

عيادة سكري الأطفال, تلفون: 0096227200600

تمّ مراجعة الدراسة و الموافقة عليها من قبل لجان أخلاقيات البحوث العلمية في مستشفى الملك المؤسس عبدالله الجامعي (الأردن) و جامعة تكساس (هيوستن, الولايات المتحدة الأمريكية).

Appendix E

Informed Consent – English Version

Date: …… **Participant Code Number:** ……

Patient consent form for conducting scientific research

Patient Name: …….…… MRN #.....

Name of the Researcher: ……Phone # …….

Study Title: ……

Before I agreed to participate in the research I was informed by the researcher with the following:

1. Approval by the concerned authorities in the hospital for conducting the study
2. Study objectives and procedures
3. Any potential and foreseeable risks and any inconvenience or benefits arising from the study
4. Any alternative or potential procedures or treatments
5. Unexpected risk potential
6. Any compensation or insured medical treatment in the event of harm or damage as a result of the study
7. Duration of the study
8. Data confidentiality procedure
9. Cases that may prompt the researcher to stop me from participating in the study
10. Any additional effort I could make for the study.
11. What happens if I decide to withdraw from the study?
12. When should I be informed of new conclusions that may affect my determination to participate in the study

If you have questions about your rights as a participant in this study or what you should do if you are harmed, you can call at any time:
Name:……..Phone…….

Your participation in this study is voluntary and optional. You will not be penalized or lose any benefits if you decide not to participate or withdraw from the study at any time. Once you sign this document you acknowledge that you agree to voluntarily participate in this study and that the above information is fully explained.

Date ----------	Name of the Participant ----------	Signature ----------
Date ---------- Date ----------	First Witness ---------- Second Witness ----------	Signature ---------- Signature ----------
Date ----------	Name of the Researcher ----------	Signature ----------

Important Note: A copy of this form must be saved in the patient's medical file

Appendix F

Informed Consent – Arabic Version

Date: ..... **Participant Code Number:** .....

نموذج موافقة المريض على إجراء بحث علمي

إسم المريض: ..... الرقم الطبي: .....

إسم المشرف على البحث: ..... رقم الهاتف: .....

عنوان البحث: .....

- قبل موافقتي على المشاركة في البحث تم إعلامي من قبل الباحث بما يلي:
  1. موافقة الجهات المعنية في المستشفى على إجراء البحث.
  2. أهداف البحث و إجراءاته.
  3. أيّة أخطار ممكنة و متوقعة و أيّة مضايقات أو منافع ناتجه عن البحث.
  4. أيّة إجراءات أو علاجات بديلة أو محتملة.
  5. إحتمال خطورة غير متوقعة.
  6. أيّة تعويضات أو علاج طبي مؤمّن لي في حال حدوث أذى أو ضرر ما نتيجة البحث
  7. المدة الزمنية اللازمة للبحث.
  8. كيفية الحفاظ على سرّية المعلومات.
  9. الحالات التي من الممكن أن تحث الباحث على إيقافي عن المشاركة في البحث.
  10. إي جهد إضافي ممكن أن أبذله لغاية البحث.
  11. ماذا يحدث في حال قررت أن اتوقف عن المشاركة في البحث.
  12. متى يتوجب إعلامي بإستنتاجات جديدة ممكن أن تؤثر على عزمتي في المشاركة في البحث.
- إذا كان لديك أسئلة ما تتعلق بحقوقك كمشارك في هذا البحث أو فيما يتوجب عليك عمله في حال إصابتك بأذى إو ضرر فمن الممكن الإتصال في أي وقت من الأوقات ب:

..... على الرقم .....

- مشاركتك في هذا البحث إختيارية فلن تعاقب أو تخسر أيّة منافع في حال قررت عدم المشاركة أو الإنسحاب من الدراسة في أي وقت.
- بمجرد توقيعك على هذا المستند فأنت تُقر بأنك توافق إختياريا على المشاركة في هذه الدراسة و أن المعلومات المدونه أعلاه شُرحت بالكامل.

التاريخ	إسم المشارك	توقيعه .....
التاريخ	إسم الشاهد الأول	توقيعه .....
التاريخ	إسم الشاهد الثاني	توقيعه .....
التاريخ	إسم المشرف على البحث	توقيعه .....

- ملاحظة هامة: يجب حفظ نسخة من هذا النموذج في الملف الطبي للمشارك

Appendix G

The Pediatric Quality of Life Inventory 3.0 Diabetes Module – English Version

PedsQL ™

Diabetes Module

Version 3.0

TEEN REPORT (ages 13-18)

DIRECTIONS

Teens with diabetes sometimes have special problems. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

UTHealth The University of Texas Health Science Center at Houston
IRB NUMBER: HSC-SN-17-0852
IRB APPROVAL DATE: 10/10/2017

Date: ..... **Participant Code Number:** .....

PedsQL 2

*In the past **ONE month,** how much of a **problem** has this been for you …*

ABOUT MY DIABETES *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I feel hungry	0	1	2	3	4
2. I feel thirsty	0	1	2	3	4
3. I have to go to the bathroom too often	0	1	2	3	4
4. I have stomachaches	0	1	2	3	4
5. I have headaches	0	1	2	3	4
6. I go "low"	0	1	2	3	4
7. I feel tired or fatigued	0	1	2	3	4
8. I get shaky	0	1	2	3	4
9. I get sweaty	0	1	2	3	4
10. I have trouble sleeping	0	1	2	3	4
11. I get irritable	0	1	2	3	4

TREATMENT - I *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It hurts to prick my finger or give insulin shots	0	1	2	3	4
2. I am embarrassed about having diabetes	0	1	2	3	4
3. My parents and I argue about my diabetes care	0	1	2	3	4
4. It is hard for me to stick to my diabetes care plan	0	1	2	3	4

*Whether you do these things **on your own or with the help of your parents**, please answer how hard these things were to do in the past **ONE month**.*

TREATMENT II - *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to take blood glucose tests	0	1	2	3	4
2. It is hard for me to take insulin shots	0	1	2	3	4
3. It is hard for me to exercise	0	1	2	3	4
4. It is hard for me to keep track of carbohydrates or exchanges	0	1	2	3	4
5. It is hard for me to wear my id bracelet	0	1	2	3	4
6. It is hard for me to carry a fast-acting carbohydrate	0	1	2	3	4
7. It is hard for me to eat snacks	0	1	2	3	4

WORRY *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I worry about "going low"	0	1	2	3	4
2. I worry about whether or not my medical treatments are working	0	1	2	3	4
3. I worry about long-term complications from diabetes	0	1	2	3	4

Date: ..... **Participant Code Number:** .....

PedsQL 3

*In the past **ONE month,** how much of a **problem** has this been for you …*

COMMUNICATION ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4

Date: ..... **Participant Code Number:** .....

PedsQL ™
Diabetes Module

Version 3.0

PARENT REPORT for **TEENS** (ages **13-18**)

DIRECTIONS

Teens with diabetes sometimes have special problems. On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Date: ..... **Participant Code Number:** .....

Peds QL 2

*In the past **ONE month,** how much of a **problem** has your teen had with …*

DIABETES *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling hungry	0	1	2	3	4
2. Feeling thirsty	0	1	2	3	4
3. Having to go to the bathroom too often	0	1	2	3	4
4. Having stomachaches	0	1	2	3	4
5. Having headaches	0	1	2	3	4
6. Going "low"	0	1	2	3	4
7. Feeling tired or fatigued	0	1	2	3	4
8. Getting shaky	0	1	2	3	4
9. Getting sweaty	0	1	2	3	4
10. Having trouble sleeping	0	1	2	3	4
11. Getting irritable	0	1	2	3	4

TREATMENT - I *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Needle sticks (i.e. injections/blood tests) causing him/her pain	0	1	2	3	4
2. Getting embarrassed about having diabetes	0	1	2	3	4
3. Arguing with me or my spouse about diabetes care	0	1	2	3	4
4. Sticking to his/her diabetes care plan	0	1	2	3	4

*Whether your teen does these things **independently or with your help**, please answer how difficult these things were to do in the past **ONE month**. (Note: This section is **not** asking about your teen's independence in these areas, just how hard they were to do).*

TREATMENT - II (*problems with…*)	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for my teen to take blood glucose tests	0	1	2	3	4
2. It is hard for my teen to take insulin shots	0	1	2	3	4
3. It is hard for my teen to exercise	0	1	2	3	4
4. It is hard for my teen to track carbohydrates or exchanges	0	1	2	3	4
5. It is hard for my teen to wear his/her id bracelet	0	1	2	3	4
6. It is hard for my teen to carry a fast-acting carbohydrate	0	1	2	3	4
7. It is hard for my teen to eat snacks	0	1	2	3	4

WORRY *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Worrying about "going low"	0	1	2	3	4
2. Worrying about whether or not medical treatments are working	0	1	2	3	4
3. Worrying about long-term complications of diabetes	0	1	2	3	4

Date: ..... **Participant Code Number:** .....

*In the past **ONE month,** how much of a **problem** has your teen had with …*

Peds QL 3

COMMUNICATION ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Telling the doctors and nurses how he/she feels	0	1	2	3	4
2. Asking the doctors or nurses questions	0	1	2	3	4
3. Explaining his/her illness to other people	0	1	2	3	4

Appendix H

The Pediatric Quality of Life Inventory 3.0 Diabetes Module – Arabic Version

رقم البطاقة الشخصية_____

التاريخ:_____

PedsQL™

استطلاع مرض السكر

Version 3.0 - Arabic (Jordan)

تقرير المراهقين (للأعمار **13-18**)

التوجيهات

في بعض الأحيان، يواجه المراهقون الذين يعانون من مرض السكر مشاكل ذات طابع

0 إذا كان لا يمثل مشكلة **أبدًا**
1 إذا كان **نادرًا** ما يمثل مشكلة
2 إذا كان **أحيانًا** ما يمثل مشكلة
3 إذا كان **غالبًا** ما يمثل مشكلة
4 إذا كان **دائمًا تقريبًا** ما يمثل مشكلة

ليست هناك إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/تفهمي سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

PedsQL – Jordan/Arabic – Version of 11 Jun 12 – MAPI Institute.
ID6710 / PedsQL-3.0-Diabetes-A_AU3.0_ara-JO.doc
UTHealth The University of Texas Health Science Center at Houston
IRB NUMBER: HSC-SN-17-0852
IRB APPROVAL DATE: 10/10/2017

PedsQL2

*خلال الـ **4 أسابيع** الماضية، ما مدى **المشكلة** التي كان يمثلها لك ذلك ...*

عن مرض السكر *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أشعر بالجوع	0	1	2	3	4
2. أشعر بالعطش	0	1	2	3	4
3. يجب أن أذهب إلى الحمام مرات كثيرة جدًا	0	1	2	3	4
4. عندي مغص	0	1	2	3	4
5. عندي صداع	0	1	2	3	4
6. "ينخفض مستوى السكر في دمي"	0	1	2	3	4
7. أشعر بالتعب	0	1	2	3	4
8. أشعر برعشة	0	1	2	3	4
9. أتبلّل من العرق	0	1	2	3	4
10. لا أنام جيدًا	0	1	2	3	4
11. أصبحت أنفعل بسرعة	0	1	2	3	4

العلاج - 1 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أتألم عند وخز إصبعي أو إعطاء حقن الإنسولين	0	1	2	3	4
2. أشعر بالحرج من مرض السكر	0	1	2	3	4
3. أتجادل أنا ووالديّ حول الرعاية الخاصة بمرض السكر	0	1	2	3	4
4. من الصعب عليّ أن ألتزم بخطة الرعاية الخاصة بمرض السكر	0	1	2	3	4

*سواء كنت تفعل/تفعلي هذه الأشياء **وحدك أو بمساعدة والديك**، من فضلك قُل/قولي مدى صعوبة قيامك بهذه الأشياء خلال الـ **4 أسابيع** الماضية.*

العلاج - 2 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. من الصعب عليّ إجراء اختبار السكر في الدم	0	1	2	3	4
2. من الصعب عليّ أخذ حقن الإنسولين	0	1	2	3	4
3. من الصعب عليّ ممارسة الأنشطة البدنية	0	1	2	3	4
4. من الصعب عليّ مراقبة كمية الكربوهيدرات أو البدائل	0	1	2	3	4
5. من الصعب عليّ ارتداء سوار بيانات مرض السكر	0	1	2	3	4
6. من الصعب عليّ حمل كربوهيدرات سريعة المفعول معي	0	1	2	3	4
7. من الصعب عليّ تناول الوجبات الخفيفة	0	1	2	3	4

القلق *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أقلق أن "ينخفض مستوى السكر في دمي"	0	1	2	3	4
2. أقلق حول ما إذا كانت العلاجات الطبية التي أتلقاها ناجحة أم لا	0	1	2	3	4
3. أقلق من المضاعفات طويلة المدى الناتجة عن مرض السكر	0	1	2	3	4

PedsQL3

*خلال الـ **4** **أسابيع** الماضية، ما مدى **المشكلة** التي كان يمثلها لك ذلك ...*

التواصل *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. من الصعب عليّ أن أقول للأطباء والممرضين ما أشعر به	0	1	2	3	4
2. من الصعب عليّ أن أطرح أسئلة على الأطباء والممرضين	0	1	2	3	4
3. من الصعب عليّ أن أشرح مرضي للآخرين	0	1	2	3	4

IRB NUMBER: HSC-SN-17-0852
IRB APPROVAL DATE: 10/10/2017

رقم البطاقة الشخصية_____

التاريخ:_____

PedsQL™

استطلاع مرض السكر

Version 3.0 - Arabic (Jordan)

تقرير وليّ الأمر الخاص **بالمراهقين** (للأعمار **13-18**)

التوجيهات

في بعض الأحيان، يواجه المراهقون الذين يعانون من مرض السكر مشاكل ذات طابع

0 إذا كان لا يمثل مشكلة **أبدًا**
1 إذا كان **نادرًا** ما يمثل مشكلة
2 إذا كان **أحيانًا** ما يمثل مشكلة
3 إذا كان **غالبًا** ما يمثل مشكلة
4 إذا كان **دائمًا تقريبًا** ما يمثل مشكلة

ليست هناك إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/تفهمي سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

PedsQL 2

*خلال الـ **4 أسابيع** الماضية، ما مدى **المشكلة** التي عانى منها ابنك المراهق/ابنتك المراهقة ...*

مرض السكر *(مشاكل مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. الشعور بالجوع	0	1	2	3	4
2. الشعور بالعطش	0	1	2	3	4
3. ضرورة الذهاب إلى الحمام مرات كثيرة جدًا	0	1	2	3	4
4. الشعور بمغص	0	1	2	3	4
5. الشعور بصداع	0	1	2	3	4
6. "ينخفض مستوى السكر في دمه"	0	1	2	3	4
7. الشعور بالتعب	0	1	2	3	4
8. الشعور بالرعشة	0	1	2	3	4
9. التبلّل من العرق	0	1	2	3	4
10. وجود صعوبة في النوم	0	1	2	3	4
11. أصبح سريع الانفعال	0	1	2	3	4

العلاج - 1 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. وخز الإبر (أي الحقن/اختبارات الدم) التي تسبب له/لها ألمًا	0	1	2	3	4
2. الشعور بالحرج من الإصابة بمرض السكر	0	1	2	3	4
3. المجادلة معي أو مع زوجي/زوجتي حول الرعاية الخاصة بمرض السكر	0	1	2	3	4
4. الالتزام بخطة الرعاية الخاصة بمرض السكر	0	1	2	3	4

*سواء كان ابنك المراهق/ابنتك المراهقة يفعل هذه الأشياء **وحده أو بمساعدتك**، من فضلك قل/قولي مدى صعوبة القيام بهذه الأشياء خلال الـ **4 أسابيع** الماضية. (ملحوظة: هذا القسم **لا** يسأل عن استقلال ابنك المراهق/ابنتك المراهقة في هذه المجالات، بل يسأل فقط عن مدى صعوبة القيام بها.)*

العلاج - 2 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. من الصعب على ابني المراهق/ابنتي المراهقة إجراء اختبار السكر في الدم	0	1	2	3	4
2. من الصعب على ابني المراهق/ابنتي المراهقة أخذ حقن الإنسولين	0	1	2	3	4
3. من الصعب على ابني المراهق/ابنتي المراهقة ممارسة الأنشطة البدنية	0	1	2	3	4
4. من الصعب على ابني المراهق/ابنتي المراهقة مراقبة كمية الكربوهيدرات أو البدائل	0	1	2	3	4
5. من الصعب على ابني المراهق/ابنتي المراهقة ارتداء سوار بيانات مرض السكر	0	1	2	3	4
6. من الصعب على ابني المراهق/ابنتي المراهقة حمل كربوهيدرات سريعة المفعول معه	0	1	2	3	4
7. من الصعب على ابني المراهق/ابنتي المراهقة تناول الوجبات الخفيفة	0	1	2	3	4

القلق *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. القلق من "انخفاض السكر في دمه"	0	1	2	3	4
2. القلق حول ما إذا كانت العلاجات الطبية التي يتلقاها ناجحة أم لا	0	1	2	3	4
3. القلق من المضاعفات طويلة المدى الناتجة عن مرض السكر	0	1	2	3	4

خلال ***الـ 4 أسابيع*** *الماضية، ما مدى* ***المشكلة*** *التى عانى منها ابنك المراهق/ابنتك المراهقة...*

التواصل *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أن تقول /تقولي للأطباء والممرضين ما يشعر به	0	1	2	3	4
2. طرح أسئلة على الأطباء والممرضين	0	1	2	3	4
3. شرح مرضه للآخرين	0	1	2	3	4

رقم البطاقة الشخصية_____

التاريخ:_____

PedsQL™

استطلاع مرض السكر

Version 3.0 - Arabic (Jordan)

تقرير الأطفال (للأعمار **8-12**)

التوجيهات

في بعض الأحيان، يواجه الأطفال الذين يعانون من مرض السكر مشاكل ذات طابع خاص.

0 إذا كان لا يمثل مشكلة **أبدًا**
1 إذا كان **نادرًا** ما يمثل مشكلة
2 إذا كان **أحيانًا** ما يمثل مشكلة
3 إذا كان **غالبًا** ما يمثل مشكلة
4 إذا كان **دائمًا تقريبًا** ما يمثل مشكلة

ليست هناك إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/تفهمي سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

PedsQL2

*خلال الـ **4** **أسابيع** الماضية، ما مدى **المشكلة** التي كان يمثلها لك ذلك ...*

عن مرض السكر *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أشعر بالجوع	0	1	2	3	4
2. أشعر بالعطش	0	1	2	3	4
3. يجب أن أذهب إلى الحمام مرات كثيرة جدًا	0	1	2	3	4
4. عندي مغص	0	1	2	3	4
5. عندي صداع	0	1	2	3	4
6. "ينخفض مستوى السكر في دمي"	0	1	2	3	4
7. أشعر بالتعب	0	1	2	3	4
8. أشعر برعشة	0	1	2	3	4
9. أتبلّل من العرق	0	1	2	3	4
10. لا أنام جيدًا	0	1	2	3	4
11. أصبحت أنفعل بسرعة	0	1	2	3	4

العلاج - 1 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أتألم عند وخز إصبعي أو إعطاء حقن الإنسولين	0	1	2	3	4
2. أشعر بالحرج من مرض السكر	0	1	2	3	4
3. أتجادل أنا ووالديّ حول الرعاية الخاصة بمرض السكر	0	1	2	3	4
4. من الصعب عليّ أن ألتزم بخطة الرعاية الخاصة بمرض السكر	0	1	2	3	4

*سواء كنت تفعل/تفعلي هذه الأشياء **وحدك أو بمساعدة والديك**، من فضلك قُل/قولي مدى صعوبة قيامك بهذه الأشياء خلال الـ **4** **أسابيع** الماضية.*

العلاج - 2 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. من الصعب عليّ إجراء اختبار السكر في الدم	0	1	2	3	4
2. من الصعب عليّ أخذ حقن الإنسولين	0	1	2	3	4
3. من الصعب عليّ ممارسة الأنشطة البدنية	0	1	2	3	4
4. من الصعب عليّ مراقبة كمية الكربوهيدرات أو البدائل	0	1	2	3	4
5. من الصعب عليّ ارتداء سوار بيانات مرض السكر	0	1	2	3	4
6. من الصعب عليّ حمل كربوهيدرات سريعة المفعول معي	0	1	2	3	4
7. من الصعب عليّ تناول الوجبات الخفيفة	0	1	2	3	4

القلق *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. أقلق أن "ينخفض مستوى السكر في دمي"	0	1	2	3	4
2. أقلق حول ما إذا كانت العلاجات الطبية التي أتلقاها ناجحة أم لا	0	1	2	3	4
3. أقلق من المضاعفات طويلة المدى الناتجة عن مرض السكر	0	1	2	3	4

PedsQL3

*خلال الـ **4** **أسابيع** الماضية، ما مدى **المشكلة** التي كان يمثلها لك ذلك ...*

التواصل *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا
1. من الصعب عليّ أن أقول للأطباء والممرضين ما أشعر به	0	1	2	3	4
2. من الصعب عليّ أن أطرح أسئلة على الأطباء والممرضين	0	1	2	3	4
3. من الصعب عليّ أن أشرح مرضي للآخرين	0	1	2	3	4

رقم البطاقة الشخصية_____

التاريخ:_____

PedsQL™

استطلاع مرض السكر

Version 3.0 - Arabic (Jordan)

تقرير وليّ الأمر الخاص **بالأطفال** (للأعمار **8-12**)

التوجيهات

في بعض الأحيان، يواجه الأطفال الذين يعانون من مرض السكر مشاكل ذات طابع خاص. يوجد بالصفحة التالية قائمة بالأشياء التي قد تمثل مشكلة **لطفلك**. من فضلك قل/قولي لنا **ما مدى المشكلة** التي كان يمثلها كل مما يلي بالنسبة **لطفلك** خلال **الـ4 أسابيع الماضية** بوضع دائرة:

0 إذا كان لا يمثل مشكلة **أبدًا**
1 إذا كان **نادرًا** ما يمثل مشكلة
2 إذا كان **أحيانًا** ما يمثل مشكلة
3 إذا كان **غالبًا** ما يمثل مشكلة
4 إذا كان **دائمًا تقريبًا** ما يمثل مشكلة

ليست هناك إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/تفهمي سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

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ID6710 / PedsQL-3 0-Diabetes-PC_AU3 0_ara-JO.doc

PedsQL 2

خلال ***الـ4 أسابيع*** *الماضية، ما مدى* ***المشكلة*** *التى عانى منها طفلك ...*

مرض السكر *(مشاكل مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا تقريبًا
1. الشعور بالجوع	0	1	2	3	4
2. الشعور بالعطش	0	1	2	3	4
3. ضرورة الذهاب إلى الحمام مرات كثيرة جدًا	0	1	2	3	4
4. الشعور بمغص	0	1	2	3	4
5. الشعور بصداع	0	1	2	3	4
6. "ينخفض مستوى السكر في دمه"	0	1	2	3	4
7. الشعور بالتعب	0	1	2	3	4
8. الشعور بالرعشة	0	1	2	3	4
9. التبلّل من العرق	0	1	2	3	4
10. وجود صعوبة في النوم	0	1	2	3	4
11. أصبح سريع الانفعال	0	1	2	3	4

العلاج - 1 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا تقريبًا
1. وخز الإبر (أي الحقن/اختبارات الدم) التي تسبب له/لها ألمًا	0	1	2	3	4
2. الشعور بالحرج من الإصابة بمرض السكر	0	1	2	3	4
3. المجادلة معي أو مع زوجي/زوجتي حول الرعاية الخاصة بمرض السكر	0	1	2	3	4
4. الالتزام بخطة الرعاية الخاصة بمرض السكر	0	1	2	3	4

سواء كان طفلك يفعل هذه الأشياء ***وحده أو بمساعدتك****، من فضلك قل/قولي مدى صعوبة القيام بهذه الأشياء خلال* ***الـ4 أسابيع*** *الماضية. (ملحوظة: هذا القسم* ***لا*** *يسأل عن استقلال طفلك في هذه المجالات، بل يسأل فقط عن مدى صعوبة القيام بها.)*

العلاج - 2 *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا تقريبًا
1. من الصعب على طفلي إجراء اختبار السكر في الدم	0	1	2	3	4
2. من الصعب على طفلي أخذ حقن الإنسولين	0	1	2	3	4
3. من الصعب على طفلي ممارسة الأنشطة البدنية	0	1	2	3	4
4. من الصعب على طفلي مراقبة كمية الكربوهيدرات أو البدائل	0	1	2	3	4
5. من الصعب على طفلي ارتداء سوار بيانات مرض السكر	0	1	2	3	4
6. من الصعب على طفلي حمل كربوهيدرات سريعة المفعول معه	0	1	2	3	4
7. من الصعب على طفلي تناول الوجبات الخفيفة	0	1	2	3	4

القلق *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا تقريبًا
1. القلق من "انخفاض السكر في دمه"	0	1	2	3	4
2. القلق حول ما إذا كانت العلاجات الطبية التي يتلقاها ناجحة أم لا	0	1	2	3	4
3. القلق من المضاعفات طويلة المدى الناتجة عن مرض السكر	0	1	2	3	4

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*خلال الـ**4 أسابيع** الماضية، ما مدى **المشكلة** التي عانى منها طفلك ...*

التواصل *(مشكلات مع...)*	أبدًا	نادرًا	أحيانًا	غالبًا	دائمًا تقريبًا
1. أن تقول /تقولي للأطباء والممرضين ما يشعر به	0	1	2	3	4
2. طرح أسئلة على الأطباء والممرضين	0	1	2	3	4
3. شرح مرضه للآخرين	0	1	2	3	4

UTHealth The University of Texas Health Science Center at Houston
IRB NUMBER: HSC-SN-17-0852
IRB APPROVAL DATE: 10/10/2017

Appendix I

The International Physical Activity Questionnaire –English Version

Date: …… **Participant Code Number:** …….

International Physical Activity Questionnaire

Short Last 7 Days Self-administered Format

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?
   _____ **Days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **Hours per day**

   _____ **Minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.
   _____ **Days per week**

   ☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **Hours per day**

_____ **Minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **Days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **Hours per day**

_____ **Minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **Hours per day**

_____ **Minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Appendix J

The International Physical Activity Questionnaire –Arabic Version

Date: …… **Participant Code Number:** ……

Physical Activity Questionnaire (Arabic)

استبانة النشاط البدني الدولية

لقياس مستوى النشاط البدني في الأيام السبعة الماضية

الصيغة المختصرة للاستبانة، للاستخدام عن طريق التعبئة الشخصية

نحن مهتمون بمعرفة أنواع الأنشطة البدنية التي يقوم بها الأفراد كجزء من حياتهم اليومية. الأسئلة التالية ترتكز حول الوقت الذي قضيته في ممارسة أنشطة بدنية خلال الأيام السبعة الماضية. فضلاً أجب عن كل سؤال من الأسئلة التالية حتى وإن كنت تعتبر نفسك غير نشيط بدنياً. فكر في الأنشطة البدنية التي تمارسها خلال عملك، وكجزء من أعمالك المنزلية، وأثناء تنقلك من مكان لآخر، وتلك التي تقوم بها في وقت فراغك بغرض الترويح أو التمرين أو الرياضة.

الآن فكر في جميع الأنشطة البدنية التي تتطلب جهداً بدنياً مرتفع الشدة والتي قمت بممارستها خلال الأيام السبعة الماضية. الأنشطة البدنية مرتفعة الشدة هي تلك الأنشطة التي تجعل تنفسك أعلى بكثير من المعتاد، مثل رفع أشياء ثقيلة، أو حرث الأرض، أو ركوب الدراجة بسرعة عالية، أو الجري، أو ممارسة كرة القدم، أو كرة السلة، أو السباحة، أو نط الحبل. فكر فقط في الأنشطة البدنية مرتفعة الشدة التي قمت بممارستها لمدة 10 دقائق على الأقل في كل مرة.

1- خلال الأيام السبعة الماضية، كم يوماً مارست فيه نشاطاً بدنياً مرتفع الشدة؟

____ يوم في الأسبوع

☐ **لا أقوم بأي نشاط بدني مرتفع الشدة.** ⟵ **انتقل مباشرة إلى السؤال رقم 3**

2- في المعتاد، كم من الوقت قضيته في ممارسة نشاط بدني مرتفع الشدة في أحد تلك الأيام؟

____ ساعة في اليوم

____ دقيقة في اليوم

☐ **لا أدري/ أو غير متأكد.**

الآن فكر في جميع الأنشطة البدنية التي تتطلب جهداً بدنياً معتدل الشدة والتي قمت بممارستها خلال الأيام السبعة الماضية. الأنشطة البدنية معتدلة الشدة هي تلك الأنشطة التي تجعل تنفسك أعلى من المعتاد إلى حداً ما، ويمكن أن تتضمن رفع أشياء خفيفة، أو ركوب الدراجة بسرعة عادية، أو ممارسة كرة الطائرة، أو ممارسة تنس الطاولة، أو كنس المنزل، أو غسل الملابس يدوياً، أو غسل السيارة. لا تحسب المشي ضمن هذه الأنشطة. مرة أخرى، فكر فقط في الأنشطة البدنية معتدلة الشدة التي قمت بممارستها لمدة 10 دقائق على الأقل في كل مرة.

3- خلال الأيام السبعة الماضية، كم يوماً مارست فيه نشاطاً بدنياً معتدل الشدة؟

____ يوم في الأسبوع

☐ **لا أقوم بأي نشاط بدني معتدل الشدة.** ⟵ **انتقل مباشرة إلى السؤال رقم 5**

4- في المعتاد، كم من الوقت قضيته في ممارسة نشاط بدني معتدل الشدة في أحد تلك الأيام؟

____ ساعة في اليوم

____ دقيقة في اليوم

☐ **لا أدري/ أو غير متأكد.**

الآن فكر في الوقت الذي قضيته في المشي خلال الأيام السبع الماضية، ويتضمن ذلك المشي إلى العمل، والمشي أثناء العمل، وفي البيت، وخلال انتقالك من مكان لآخر، أو أي نوع من أنواع المشي بغرض الترويح أو الرياضة.

5- خلال الأيام السبعة الماضية، كم يوماً مارست فيه المشي لمدة 10 دقائق على الأقل في كل مرة؟

____ يوم في الأسبوع

☐ **لا أقوم بممارسة المشي إطلاقا.** ⟵ **انتقل مباشرة إلى السؤال رقم 7**

6- في المعتاد، كم من الوقت قضيته في ممارسة المشي في أحد تلك الأيام؟

____ ساعة في اليوم

____ دقيقة في اليوم

☐ **لا أدري/ أو غير متأكد.**

الآن فكر في الوقت الذي قضيته جالساً خلال الأيام السبعة الماضية. أحسب وقت الجلوس في العمل، وفي المنزل، وفي الدراسة، وفي الترفيه. من الممكن أن يتضمن ذلك وقت الجلوس على المكتب، وأثناء العمل على الكمبيوتر، وأثناء زيارتك لصديق، وأثناء القراءة، والجلوس أو الاستلقاء لمشاهدة التلفزيون.

7- خلال الأيام السبعة الماضية، كم من الوقت قضيته جالساً في أحد هذه الأيام من غير أيام الإجازة الأسبوعية؟

____ ساعة في اليوم

____ دقيقة في اليوم

☐ **لا أدري/ أو غير متأكد.**

(نهاية الاستبانة، شكراً لمشاركتكم)

Appendix K

The Summary of Diabetes Self- Care Activities–Arabic (SDSCA-Arabic) Questionnaire

Date: ..... **Participant Code Number:** .....

Appendix C: Adherence Questionnaire

ملخص أنشطة العناية الشخصية لمرض السكري : للاستخدام بواسطة التعبئة الشخصية

نحن مهتمون بمعرفة أنشطة العناية الشخصية التي تقوم بها كجزء من العلاج كمريض سكري خلال الأيام السبعة الماضية. فضلاً أجب عن كل سؤال من الأسئلة التالية:

No.	Items	الأجابة	السؤال	التسلسل
	Diet		**التغذية**	
1	During the last seven days, for how many days did you follow a healthy diet?	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي اتبعت فيها نظام غذاء صحي؟	1
2	How well did you follow your diet during the last month (rate of days in the week)	0-1-2-3-4-5-6-7	ما مدى إتباعك لنظامك الغذائي خلال الشهر الماضي (كم معدل عدد الأيام خلال الأسبوع) ؟	2
	Exercise		**الرياضة**	
3	During the last seven days, for how many days did you practice physical activities in general for at least 30 minutes?(Total minutes of activities including walking)	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي مارست فيها في أنشطة بدنيةبصفة عامة لمدة 30 دقيقة على الأقل (مجموع الدقائق الكلية للأنشطة بما فيها المشي)	3
4	During the last seven days, for how many days did you practice a strict training exercise session (such as swimming, walking ...etc) exclude activities that are performed around your house or at your work?	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي مارست فيها في جلسة تمرين رياضي محدد (السباحة, المشي ...الخ) عدا تلك التي تقوم بها في محيط منزلك أو اللتي تكون جزءاً من عملك؟	4
	Blood Sugar Testing		**فحص سكر الدم**	
5	During the last seven days, for how many days did you test your blood sugar level?	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي فحصت فيها سكرالدم؟	5
6	During the last seven days, for how many days did you test your blood sugar level according to your physician's instructions?	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي فحصت فيها سكر الدم حسب العدد المذكور في تعليمات طبيبك؟	6
	Foot Care		**العناية بالقدم**	
7	During the last seven days, for how many days did you check your feet?	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي فحصت فيها قدميك؟	7
8	During the last seven days, for how many days did you check the interior of your shoes (to insure that there are no materials that could cause any injury to your feet)?	0-1-2-3-4-5-6-7	خلال السبعة أيام الماضية, كم عدد الأيام التي فحصت فيها حذائك من الداخل (للتأكد من عدم وجود اشياء تسبب الجروح مثل قطع في الحذاء أو نتوءات)؟	8

You Thank ,Questionnaire the of End

(نهاية الاستبانة، شكراً لمشاركتكم)

Appendix L

The Summary of Diabetes Self- Care Activities Questionnaire - English Version

Summary of Diabetes Self-Care Activities Questionnaire

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

Number of Days

1. How many of the last SEVEN DAYS have you followed a healthful eating plan? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

4. On how many of the last SEVEN DAYS did you eat high-fat foods, such as red meat or full-fat dairy products? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Physical Activity

5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

   (Total minutes of continuous activity,including walking).

6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Blood Sugar Testing

7. On how many of the last SEVEN DAYS did you test your blood sugar? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Number of Days

8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health-care provider? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Foot Care

9. On how many of the last SEVEN DAYS did you check your feet? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes? ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Smoking

11. Have you smoked a cigarette, even a puff, in the past SEVEN DAYS? ☐0 No ☐1 Yes

11a. How many cigarettes did you smoke on an average day?

Number of cigarettes: _____

Appendix M

HbA1c Data Sheet

Date: …… **Participant Code Number:** ……

HbA1C Data

The last three measurements (taken over 12 months) if available

(*To be filled by the clinic staff*)

No.	Value %	Date of the test
Average *(To be calculated by the researcher)*		**Signature**

Appendix N

Demographic Data Questionnaire – English Version

Date: …… **Participant Code Number:** ……

Demographic Data Questionnaire

❖ Who is answering the general questions of this questionnaire?

☐ The Participant ☐ His Father ☐ His Mother ☐ Other (Please specify…….)

- Please answer each question as accurately as possible by circling the correct answer or filling in the space provided.

1. What is your age? _____

2. What is your gender? ☐ Female ☐ Male

3. Are you currently a student? ☐ Yes ☐ No

- If (Yes), what is your grade? _____

4. Parents marital status: ☐ Married ☐ Divorced

5. Do you live with both of them? ☐ Yes ☐ No

- If (No), what is the reason? ☐Death ☐Divorced ☐Father's travel abroad

6. What is the highest level of education your father has completed?

☐ Less than high school degree
☐ High school degree or equivalent
☐ College degree
☐ Bachelor degree
☐ Master degree
☐ Doctoral degree

7. What is the highest level of education your mother has completed?

☐ Less than high school degree
☐ High school degree or equivalent
☐ College degree
☐ Bachelor degree
☐ Master degree
☐ Doctoral degree

8. What is your father employment status?

☐ Unemployed
☐ Part-time
☐ Full-time

9. What is your mother employment status?

☐ Unemployed

☐ Part-time

☐ Full-time

10. For how long you have been diagnosed with diabetes?

☐1 - <2 years ☐2 - <3 years ☐3 - <4 years ☐4 - <5 years ☐5 years or more

11. Age at diagnosis: _____

12. Has any of your family members diagnosed with diabetes? ☐ Yes ☐ No

- If yes, who:

☐ Father ☐ Mother ☐ Brother ☐ Sister

13. What other medical conditions or diseases do you have other than type 1 diabetes?

☐ Cystic fibrosis

☐ Asthma

☐ Cardiovascular disease

☐ Kidney diseases

☐ Autoimmune disease (Please specify……..)

☐ Eating disorder

☐ Depression

☐ Other (Please specify……..)

☐ Don't know

14. What is your height? _____cm

15. What is your weight? _____kg

16. What is the mode of insulin delivery? ☐ Daily insulin injections ☐ Insulin pump

- If on Daily injections, number of injections per day _____
- How often is your blood sugar measured per day? _____

17. Do you have health insurance coverage? ☐ Yes ☐ No

18. How many times have you been hospitalized due to diabetes last year? _____

19. How many episodes of hypoglycemia have you reported last month? _____

Thank you for completing this personal profile

Appendix O

Demographic Data Questionnaire – Arabic Version

Date: …… **Participant Code Number:** ……

إستبيان المعلومات الشخصية

- **من يجيب على الأسئلة العامة لهذا الاستبيان؟**

المشارك ☐ الأب ☐ الأم ☐ أحد أخر (الرجاء التحديد .....)
☐

- **يرجى الإجابة على كل سؤال بأكبر قدر ممكن من الدقة عن طريق إختيار الإجابة الصحيحة أو ملء المساحة المتوفرة.**

1. **العمر** ..... سنة
2. **الجنس** ☐ ذكر ☐ أنثى
3. **هل أنت ملتحق بالمدرسة حاليا؟** ☐ نعم ☐ لا
   - إذا كانت الإجابة ب (**نعم**), الرجاء تحديد مستى الصف الدراسي .....
4. **الحالة الإجتماعية للأبوين:** ☐ متزوجيين ☐ مطلقين
5. **هل تعيش مع كليهما:** ☐ نعم ☐ لا
   - إذا كانت الإجابة ب (**لا**), فما هو السبب؟ ☐ الطلاق ☐ الوفاة ☐ سفر الأب الى الخارج
6. **ما هو المستوى التعليمي للأب؟**
   - ☐ أقل من الثانوية العامة
   - ☐ الثانوية العامة أو ما يعادلها
   - ☐ دبلوم كلّية
   - ☐ درجة جامعية- بكالوريوس
   - ☐ درجة جامعية- ماجستير
   - ☐ درجة جامعية- دكتوراة
7. **ما هي طبيعة عمل الأب؟**
   - ☐ بدون عمل
   - ☐ وظيفة بدوام جزيء
   - ☐ وظيفة بدوام كامل

8. ما هو المستوى التعليمي للأم؟

☐ أقل من الثانوية العامة

☐ الثانوية العامة أو ما يعادلها

☐ دبلوم كلّية

☐ درجة جامعية- بكالوريوس

☐ درجة جامعية- ماجستير

☐ درجة جامعية- دكتوراة

9. ما هي طبيعة عمل الأم؟

☐ بدون عمل

☐ وظيفة بدوام جزيء

☐ وظيفة بدوام كامل

10. منذ متى تم تشخيصك بمرض السكري؟

☐ سنة إلى أقل من سنتين

☐ سنتين إلى أقل من 3 سنوات

☐ 3 سنوات إلى أقل من 4 سنوات

☐ 4 سنوات إلى أقل من 5 سنوات

☐ 5 سنوات أو أكثر

11. العمر عند التشخيص: ..... سنة

12. هل هناك أحد من أفراد عائلتك مصاب بالسكري؟ ☐ نعم ☐ لا

♦ إذا كانت الإجابة ب (نعم), الرجاء الإشارة ب (√) على الشخص:

☐ الأب ☐ الأم ☐ الأخ ☐ الأخت

13. هل تعاني من أي من الأمراض التالية بالإضافه لمرض السكري؟

☐ التليّف الكيسي

☐ الربو

☐ أمراض القلب و الشرايين

- ☐ أمراض الكلى
- ☐ أمراض المناعة (الرجاء التحديد.....)
- ☐ إضطرابات الأكل
- ☐ الأكتئاب
- ☐ أمراض أخرى (الرجاء التحديد.....)
- ☐ لا أعرف

14. الطول: ..... سم

15. الورن: ..... كغم

16. ما هي الكيفية التي تتناول بها جرعة الأنسولين؟

- ☐ حُقن الإنسولين اليومية (الحقن تحت الجلد)
- ☐ جهاز مضخة الأنسولين
- ♦ إذا كانت الإجابة ب (حُقن الإنسولين اليومية), كم هو عدد الحُقن يومياً .....
- ♦ كم مرة يتم قياس نسبة السكر في الدم يومياً؟ .....

17. هل لديك تأمين صحي؟ ☐ نعم ☐ لا

18. كم هي عدد المرات التي كنت قد أدخلت بها المستشفى بسبب مرض السكري في العام الماضي؟
.....

19. كم هي عدد الحالات التي عانيت فيها من نقص السكر في الدم الشهر الماضي؟
.....

شكراً على إكمال هذا الإستبيان

IRB NUMBER: HSC-SN-17-0852
IRB APPROVAL DATE: 10/10/2017

Appendix P

Oral Consent Script

مستشفى الملك المؤسس عبدالله الجامعي
king Abdullah University Hospital

Oral Consent Script

I am Yousef Aljawarneh, a Nursing PhD student at University of Texas Health Science Center at Houston, USA, and I am currently working on my PhD dissertation. I am conducting a research study on “the effects of physical activity, health-related quality of life, and adherence on glycemic control in adolescents with type 1 diabetes”. The study will help me understand the association between these variables and will hopefully provide more information and understanding of the factors that facilitate disease management and develop interventions that can improve medical and psychosocial outcomes of T1D.

I would like to ask for your voluntary participation in the study. If you agree to participate I will ask you to fill three questionnaires which should take approximately 15 minutes. If you do not wish to participate, you may stop at any time. All obtained information will be completely anonymous, your name will not appear anywhere in the final report, and the information will be used for research purposes only. There are no risks associated with your participation. There are no direct benefits from participation in the study; however, findings of the study may help health care providers to promote better management and care. If you would like a copy of this letter for your records, please let me know and I will give you a copy.

If you have any questions regarding the study, please contact:

- Yousef Aljawarneh, Mobile: 00962798097033
- Dr. Mohammad Aljarrah, Mobile: 00962798167489
- Clinic Nurse, Mobile, 0096227200600

The study has been reviewed and approved by the Research Ethics Committees at KAUH (Jordan) and UTHealth (USA)

Thank you

UTHealth
The University of Texas Health Science Center at Houston

IRB NUMBER: HSC-SN-17-0852

IRB APPROVAL DATE: 10/10/2017

Appendix Q

Enrolment Log

Screening and Enrollment Log

Study Title:	IRB Approval:	Researcher Name:

Title: Site screening and enrollment sheet.

Purpose: To record screening and enrollment of all participants.

User: Principal investigator

Description: the sheet provides a list of all participants who were approached for enrollment and screened for eligibility. The sheet should include all participants who were approached, screened, eligible, non-eligible, and consented. The sheet will not contain any identifying information. Each sheet contains a total of 10 screenings

Screening and Enrollment Log

Participant Code Number	Screening Date (DD/MM/YY)	Eligible (Yes/No)	Ineligibility Reasons (Select numbers from the list below)	Consent Signed (Yes/No)	Questionnaires Completed			HbA1C (Yes/No)	Investigator Comments
					HRQoL (Yes/No)	PA (Yes/No)	Adherence (Yes/No)		

- **Eligibility Criteria:**
  1. Have been diagnosed with Type 1 Diabetes for more than 1 year.
  2. 12 to 18 years old.
  3. In good general health.
- **Ineligibility Reasons**
  1. Have a medical condition that interferes with physical activity recommendations.
  2. Have been diagnosed with Type 1 Diabetes for ***Less*** than 1 year.
  3. Younger than 12 years old

Appendix R

Human Subjects Protection Training: CITI Completion Report

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Yousef Aljawarneh (ID: 5372133)
- **Email:** yousef.m.aljawarneh@uth.tmc.edu
- **Institution Affiliation:** University of Texas Health Science Center at Houston (ID: 661)
- **Phone:** 6822415917

- **Curriculum Group:** CITI Good Clinical Practice Gradebook
- **Course Learner Group:** GCP
- **Stage:** Stage 1 - Basic Course
- **Description:** **This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.**

- **Report ID:** 18622074
- **Completion Date:** 02/05/2016
- **Expiration Date:** 02/04/2018
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	02/04/16
Overview of New Drug Development (ID: 1351)	02/04/16
Overview of ICH GCP (ID: 1352)	02/04/16
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	02/04/16
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	02/04/16
Investigator Obligations in FDA-Regulated Research (ID: 1356)	02/04/16
Managing Investigational Agents According to GCP Requirements (ID: 1357)	02/04/16
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	02/05/16
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	02/05/16
Detecting and Evaluating Adverse Events (ID: 1360)	02/05/16
Reporting Serious Adverse Events (ID: 1361)	02/05/16
Audits and Inspections of Clinical Trials (ID: 1363)	02/05/16
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	02/05/16
Completing the CITI GCP Course (ID: 1364)	02/05/16

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Appendix S

Study Protocol

STUDY PROTOCOL

Associations between Physical Activity, Health-Related Quality of Life, Regimen Adherence, and Glycemic Control in Jordanian Adolescents with Type 1 Diabetes

Aim: The aim of this study is to examine the associations between physical activity, health-related quality of life, adherence and glycemic control in Jordanian adolescents with type 1 diabetes (T1D).

Time Period: The study will commence between mid of October till the end of December 2017.

Setting: All data should be collected from the Pediatrics diabetes clinic at King Abdullah University Hospital (KAUH), Irbid, Jordan.

Approvals: All IRB approvals (KAUH and UTHealth) are enclosed in the operational manual within a folder named "IRB Approvals".

- The data collector needs to keep a copy of the dual IRB approval all the time when collecting data.

Role of the Principal Investigator: The Principal Investigator (Yousef Aljawarneh) will be responsible for all parts of the study including recruitment, screening, data collection, data management, data analysis, data interpretation, writing the final results and report, findings presentation, and as a communication channel between the study parties.

- His contacts:
  - Mobile (Jordan): 00962798097033
  - Mobile (United States Of America): 001-682-241-5917

- Email: Yousef.m.aljawarneh@uth.tmc.edu

Data Collection Procedure (Please skip steps if already done):

- First of all, an orientation session should be scheduled and given to the clinic staff. The session should not take more than 15 minutes. The session focuses on screening, eligibility, and accessing medical records to obtain the HbA1c values for each participant.
- The study flyer (Arabic version) needs to be posted in the clinic after consulting the charge nurse on the appropriate locations. The Arabic version can be found in the manual within a folder named "The study flyers".
- The data collection should be done within the premises of the designated clinic only. Please avoid approaching patients outside the clinic lobby.
- Before being in the clinic, please make sure to do the followings:
    - Make sufficient copies of the study documents. Make sure to copy from the original stamped copies. Copies can be found within the manual.
    - Make one copy of the following documents (The Arabic Version) for each participant: the consent form, the demographic data questionnaire, the adherence questionnaire, the physical activity questionnaire, the quality of life questionnaire, and the HbA1c data sheet.
    - Keep the Enrollment log with you all the time. The enrollment log can be found in the manual within a folder named "Questionnaires and Documents".
    - Keep sufficient stationary while in the clinic (pencils, sharper, eraser, pens). The stationery can be found in the clinic (please check with the

charge nurse) or in the co-advisor's office; Dr. Mohamed AL-jarrah (Mobile: 00962798167489).

- The clinic staff can only help in the screening and eligibility parts, they cannot ask eligible participants to sign the consent form or fill the study questionnaires.

Recruitment: Please follow the steps sequentially

- The data collector is to be stationed all the time in the clinic on Mondays and Wednesdays.
- When the data collector arrives at the clinic, notify the clinic staff to start identifying eligible participants for enrollment. If a participant found to be eligible, then approach him/her and ask for any interest in the study if his/her parents agree.
- Explain the study purpose and outcome.
- Inform him/her that the participation is voluntary.
- If a participant shows an interest to enroll after reading the flyer, please do the screening in the presence of his/her parents.
- Please do the screening in a private room at the designated clinic while waiting to be seen by their physician or after finishing their appointment when they are still in the clinic.
- If he/she does not show any interest in participation, thank the participants for their time.

- Use the “Enrollment Log” and fill the necessary data as indicated for this and each participant. In this case, the “Eligibility column” in the log should be filled with “No”. Then select from the list provided the reason for ineligibility.
- If he/she agreed to participate, thank the participants for their time and for their participation in the study.
- Use the “Enrollment Log” and fill the necessary data as indicated. Give the participant a code number. The first approached participant (eligible or not) takes number “1” in the series. The second approached participant (eligible or not) takes number “2” in the series, and so forth.
- In this case, the “Eligibility column” in the log should be filled with “Yes”.
- Obtain the consent form (Arabic version):
    - Fill in the date and participant code number.
    - Type the participant name
    - Type the participant medical record number (MRN). You can obtain it from the participant file.
    - Put the researcher name and phone number.
    - Type the short form of the study title (Glycemic control in Jordanian adolescents with Type 1 Diabetes).
    - Let the participant and his/her parents read the consent form.
    - Please clarify any query.
    - Put the PI name and Phone number for further questions (Yousef Aljawarneh, 00962798167489).

- Get the participant's signature, the first witness, the second witness, and the researcher witness.
- Make a copy of the signed consent and hand it to the clinic nurse in order to keep it in the participant's file.

- Then ask the participant to complete the following questionnaires:
  - The demographic data questionnaire (Arabic Version).
  - The adherence questionnaire (Arabic version).
  - The physical activity questionnaire (Arabic version).
  - The quality of life questionnaire (Arabic version).
    - For participants aged 13-18 years, please use the recommended version for 13-18 years old adolescents.
    - For participants aged 12 years old, please use the recommended version for 8-12 years old adolescents.
    - In case the participant can't complete the questionnaire and the parents are willing to complete it, please use the parents' proxy version.
- On each questionnaire, put the date and the participant code number.
- Again, during the distribution of the questionnaire, tell the participant that the information will be kept anonymous and participation is completely voluntary.
- Briefly explain the purpose of each questionnaire.
- Briefly explain how to respond to each item in each questionnaire.
- Advise the participant to complete each item in each questionnaire without input from others and to select only one answer for each question.

- Remain with the participant in the same room in the presence of his/her parents to answer any question or comment.
- Collect the completed questionnaires when he/she finish.
- Once finished, check that all items in each questionnaire have been answered.
- Ask each participant for any further comments and if he/she struggled with any item or was difficult to understand.
- Mark each questionnaire with the participant's code number, date, and time of completion.
- Thank the participant again.
- The singed consent form and the completed questionnaires (The demographic data questionnaire, The adherence questionnaire, The physical activity questionnaire, The quality of life questionnaire) will be attached all together in one file for each participant and labeled with the participant code number.
- At the end of each day, meet with the PI and with the co-advisor for debriefing.
- Place the collected files in the co-advisor's office in a folder labeled "Glycemic Control-Completed" with the master list of subject IDs in a locked file cabinet.

Data Management

- Data entry is the responsibility of the PI.
- Two MASTER Datasets are created in SPSS: one for the PI and one for the co-advisor for double checking the entered data (data verification).
- Both versions are located on two separate laptops (one with the PI and one in the co-advisor office).
- These datasets are named as "Glycemic-Control PI" and "Glycemic-Control CO.

- Double-check accuracy of data entry against the original participants' questionnaires with the co-advisor.

Data Analysis

- Data analysis is the responsibility of the PI.
- Please use the following scoring protocol for each questionnaire as a reference. All scoring protocols are enclosed in the study manual within a folder named "Scoring Protocols":
  - Quality of Life Questionnaire: Scoring PedsQL
  - Adherence Questionnaire: Scoring Adherence
  - Physical Activity Questionnaire: IPAQ Scoring

CURRICULUM VITAE

Yousef M. Aljawarneh, Ph.D. (c), M.C.B, R.N

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PERSONAL INFORMATION

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EDUCATION:

Institution	Year	Degree	Major
The University of Texas Health Science Center at Houston Houston, Texas, USA	2018	Ph.D.	Nursing
Jordan University of Science and Technology Irbid, Jordan	2005	M.S.	Applied Medical Sciences
Jordan University of Science and Technology Irbid, Jordan	2001	B.S.N.	Nursing

LICENSURE & CERTIFICATION

Category	Country	Certifying Body	Expiration Date
Registered Nurse	Jordan	Jordanian Nursing and Midwifery Council	2016
Registered Nurse	UAE	United Arab Emirates Nursing Council, Ministry of Health	2016
Basic Life Support	USA	American Heart Association	2018

PROFESSIONAL EXPERIENCE

Institution	Department	Position title	Dates
The University of Texas Health Science Center at Houston, Texas, USA	Acute and Continuing Nursing Care, School of Nursing	Graduate Teaching Assistant	06/2016 – Present
The University of Texas Health Science Center at Houston, Texas, USA	Family Health, School of Nursing	Academic Success Coach	05/2016 – Present
Fatima College of Health and Sciences, Al-Ain, UAE	Nursing Department and General Requirements Unit	Nursing Lecturer and Clinical Facilitator	09/2010 – 07/2015
Griffith University, Melbourne, Australia.	School of Nursing	Adjunct Lecturer	09/2010 – 07/2015
Fatima College of Health and Sciences, Al-Ain, UAE	Nursing Department	Nursing and Simulation LABs Coordinator	09/2009 – 07/2011
King Faisal Specialty Hospital and Research Centre, Riyadh, KSA	Department of Clinical Studies and Empirical Ethics	Research Assistant	08/2008 – 09/2009
King Abdullah University Hospital, Irbid, Jordan	Endoscopy Unit	Charge Nurse	04/2006 – 08/2008

King Abdullah University Hospital, Irbid, Jordan	Burn Unit	Charge Nurse	05/2005 – 04/2006
King Abdullah University Hospital, Irbid, Jordan	Medical Male Unit	Head Nurse	07/2004 – 05/2005
King Abdullah University Hospital, Irbid, Jordan	Operation Theaters	Registered Nurse	03/2002- 07/2004

PUBLICATIONS

Peer Reviewed Publications

- Hammami, M. M., **Al-Jawarneh, Y.,** Hammami, M. B., & Al Qadire, M. (2014). Information disclosure in clinical informed consent: "reasonable" patient's perception of norm in high-context communication culture. *BMC Medical Ethics, 15*(1), 3-3. doi:10.1186/1472-6939-15-3
- Hammami, M. M., Al-Gaai, E. A., **Al-Jawarneh, Y.**, Amer, H., Hammami, M. B., Eissa, A., & Qadire, M. A. (2014). Patients' perceived purpose of clinical informed consent: Mill's individual autonomy model is preferred. *BMC Medical Ethics, 15*, 2. doi:10.1186/1472-6939-15-2
- El-Akawi, Z. J., **Aljawarneh, Y. M.,** & AL-Shamayleh, Q. (2007). The change in alpha-1 antitrypsin (A1AT) plasma levels with time in newly diagnosed acute myocardial infarction (AMI) patients. *Journal of Molecular and Cellular Cardiology, 42*(6), S213-S214. doi:10.1016/j.yjmcc.2007.03.645

PRESENTATIONS

- Poster Presentation: Behavior Predictive of Texting While Driving in American Adolescents. Research Day, School of Nursing, University of Texas Health Science Center at Houston, April 2016.

PROFESSIONAL SERVICE AND MEMBERSHIP

Institution/Agency	Country	Role	Dates
The Sigma Theta Tau International Honor Society of Nursing	USA	Zeta Pi Chapter Member	03/2017-Present
Fatima College of Health and Sciences, Al-Ain, UAE	UAE	Member of Academic and Curriculum Committee, School of Nursing	2011 - 2015
Fatima College of Health and Sciences, Al-Ain, UAE	UAE	Member of the Assessment Committee, School of Nursing	2011 - 2015
Fatima College of Health and Sciences, Al-Ain, UAE	UAE	Member of the Examination and Peer Review Committee, School of Nursing	2011 - 2015
Fatima College of Health and Sciences, Al-Ain, UAE	UAE	Member of the Industry Advisory Committee, School of Nursing	2013 - 2015
Fatima College of Health and Sciences, Al-Ain, UAE	UAE	Member of the Scientific Research and Staff Development Committee, School of Nursing	2013 - 2015

VOLUNTEER WORK AND COMMUNITY SERVICE

Service Agency	Event	Country	Role	Date/s
International Operation Smile Project	Cleft Lip & Palate Care, Jordan Mission	Jordan	Operation Room Nurse	2006
Fatima College of Health and Sciences, Al-Ain, UAE	Skills for Life, Summer Campaign	UAE	Campus Coordinator	2010 - 2013
Fatima College of Health and Sciences, Al-Ain, UAE	Health & Fitness Fun Day	UAE	College Representative	2011 - 2013
United Arab Emirates University, Al-Ain, UAE	Health, Fitness and Nutrition Week	UAE	Health Educator	2013
WorldSkills Abu Dhabi, UAE	International Skills Competition	UAE	Campus Coordinator and Educator, Alain Campus at FCHS	2011 - 2013

CONFERENCES

Conference	Location	Country	Date
Currents on Gastrointestinal Medicine	Prince Hamzah Hospital	Jordan	2008
Facts on Endoscopic Retrograde CholangioPancreatography (ERCP)	Prince Hamzah Hospital	Jordan	2008
Internal Medicine Conference	King Abdullah University Hospital	Jordan	2006,2007, 2008
Ethics for Healthcare Professionals	Tawam Hospital	UAE	2010
International Nursing Conference	Fatima College of Health & Sciences	UAE	2012
Monash University Curriculum Conference	Fatima College of Health & Sciences	UAE	2012, 2013
Academic Assessment Conference	Fatima College of Health & Sciences	UAE	2012

Al-Gharbia Nursing Conference: Building and Promoting Excellence in Nursing Practice	Fatima College of Health & Sciences	UAE	2013
Health Sciences Education Curriculum Conference	Fatima College of Health & Sciences	UAE	2015

COURSES TAUGHT

Course	**Institution**	**Department**	**Didactic/ Lab, Clinical**	**Date/s**
Adult Care Nursing 1	The of Texas Health Science Center at Houston	Acute and Continuing Nursing Care	Didactic & Lab	2016-2017
Nursing Health Law and Ethics	Fatima College of Health & Sciences	Nursing	Didactic	2010-2015
Project and Presentation	Fatima College of Health & Sciences	Nursing	Didactic	2010-2014
Medical Laboratory Skills	Fatima College of Health & Sciences	Medical Laboratory	Didactic & Lab	2013
Basic Health Skills-1	Fatima College of Health & Sciences	General Requirements Unit	Didactic & Lab	2012-2015
Basic Health Skills-2	Fatima College of Health & Sciences	General Requirements Unit	Didactic & Lab	2012-2015
Medical-Surgical Nursing	Fatima College of Health & Sciences	Nursing	Clinical	2010-2014
Critical Care Nursing	Fatima College of Health & Sciences	Nursing	Clinical	2012-2013
Community Nursing	Fatima College of Health & Sciences	Nursing	Clinical	2013-2014

REFERENCES

Name	Credentials	Position	Address	Email
Geri L. Wood,	Ph.D., RN, FAAN	Coordinator, Ph.D. in Nursing Program	The University of Texas Health Science Center, School of Nursing, Houston, Texas, USA	geri.l.wood@uth.tmc.edu
Diane W. Wardell	Ph.D., RN, WHNP-BC	Professor	The University of Texas Health Science Center, School of Nursing, Houston, Texas, USA	diane.wardell@uth.tmc.edu
Muhammad D. Al-Jarrah	Ph.D., PT	Dean of the Faculty of Applied Medical Sciences	Jordan University of Science and Technology, Irbid, Jordan	jarrahm@just.edu.jo
Linda M. Brown	PhD	Assistant Professor of Nursing	The University of Texas Health Science Center, School of Nursing, Houston, Texas, USA	linda.m.brown@uth.tmc.edu
Khalid A. Jadallah	MD	Consultant Gastroenterologist and Hepatologist	King Abdullah University Hospital, Irbid, Jordan	khaled-j@just.edu.jo